GUIDE TO DAILY OPERATIONS
Introduction And Formatting

INTRODUCTION
The Guide to Daily Operations describes the procedures the Institutional Review Board (IRB) utilizes to adhere to its standard operating policies. The Guide to Daily Operations is the companion to the Standard Operating Policies. The procedures described herein, though based on policy, are flexible and take into account numerous details of the day-to-day activities of the IRB.
While this Guide is a companion to the Standard Operating Policies, this Guide is organized in a different manner. Please see the Table of Contents regarding organization of the guide.

FORMATTING
The format of each section of the guide is tailored to the needs of that specific section. Some sections include images for instructional purposes while others are limited to text only instruction. The format of each section is specialized to ensure comprehension.

After reading the content herein, any new or existing member of the IRB staff should be prepared to confidently approach any task with minimal assistance from senior staff. It is also noted here that many sections related to daily processes will make reference to other internal documents which do not appear within the guide. Those documents may include more specific instruction which may change over time without resulting in changes to this guide.
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OVERVIEW
This section details the manner in which the IRB will ensure that its policies and procedures are up to date.

PROCEDURES
The Director is responsible for overseeing the policy review process. The Director designates staff to assist in the review and revision process. The Director reviews and approves the work to ensure that revisions are appropriate and accurately reflect the current policies. Staff members review and provide comments on policies and forms. Staff members may also create draft policies and forms as assigned. Staff work is submitted to the Director for review and approval prior to implementation.

The Director, Associate Director and Assistant Director are responsible for ensuring that the IRB maintains up-to-date policies and procedures that adhere to regulatory mandates and ethical principles. They will review Policies and designate appropriate staff to review policies on an as needed basis.

Staff will review the specific policies or policy sections assigned to them by the Director and provide feedback on which sections appear out of date in response to changes in regulations, federal guidance, and policies and procedures of the University of Pennsylvania. Staff will suggest revisions to appropriately update policies. Suggested revisions, comments, and questions will be sent to the Director, Associate Director or Assistant Director for consideration. If changes are warranted, changes to the policies will be made according to the policy revision processes.

Policy Revision Processes
The Director will charge staff with drafting revised policies or creating new policies depending on the results of the policy review process. The Director will provide staff with needed background information to ensure that staff understands their assigned duties. Staff will work individually or as part of a team to create or update policies per the Director’s instructions.

Director will review the draft to determine if it is satisfactory. Once revised policies are determined to be appropriate, the Director will determine if further review by the Institutional Official is necessary. In addition, if comments from other offices within the University of Pennsylvania are needed, the Director will solicit feedback. Additional revisions may be required and the Director will determine the appropriate course for completing those revisions.

Once draft review and revisions have been completed, the Policies will be finalized and published on the IRB website. Additional publication sources within the University may be utilized at the discretion of the Director.

Form Development and Revision Processes
The Director, Associate Director, Assistant Director are responsible for ensuring that the forms, guidance, checklist, and worksheets can be appropriately used to ensure that policies are integrated into the daily operations of the IRB. They will review documents and designate appropriate staff to review forms on an as-needed basis. Senior and delegated administrative staff may also serve in this capacity.

Staff will review the specific documents assigned to them by the Director and provide feedback on whether these forms are optimal documents for ensuring meaningful reviews. Staff will suggest revisions to appropriately update documents. Suggested revisions, comments, and questions will be sent to the Director, Associate Director or Assistant Director for consideration. Forms will be updated in a manner similar to IRB Policies.
UNIT 1- IRB ORGANIZATIONAL OPERATIONS
1.1 Quality Control and Improvement

OVERVIEW
This section details quality assessment and improvement processes in place for various daily IRB activities as well as the effectiveness and compliance of the IRB and the HRPP. The section also details how staff typically work to correct errors and omissions in processes and procedures.

PROCEDURES

Quality Improvement Review of finalized IRB Minutes

All convened, expedited, and exempt review determinations are documented in the monthly IRB minutes. The minutes document is sent to the Board members for review per the federal regulations. Because of its near comprehensive documentation of IRB review activities, the minutes are a central document in the quality control review processes.

After the convened minutes have been drafted for the most recent convened board meeting and entered into Penn ERA, the complete minutes are sent via email by the board administrator to the QI Coordinator for review. The QI Coordinator reviews the minutes to ensure that they contain complete and accurate documentation of that months’ convened, expedited, and exempt reviews.

The established standards for accuracy are described in the IRB Minutes Template Guide and IRB minutes QA Checklist which is stored on the IRB Shared G; drive alongside the archive of draft and finalized IRB minutes. If errors or omissions are identified, the minutes are returned to the appropriate Board administrator for correction. The administrators then determine the appropriate course to correct the errors within the PennERA system. Once the errors are corrected, the document is prepared for finalization and sharing with the Board members at the next month’s meeting. Only minutes which have been reviewed by the QI Coordinator can be finalized and shared with the IRB members for approval.

Once the minutes are approved by the IRB members, they are stamped with a watermark including the date of approval and archived in the IRB Minutes folder on the G; Drive.

Quality Control of Daily Operations

The IRB’s day to day review procedures were designed with multiple layers of review in order to ensure that work is completed in a timely and accurate fashion. Processes involve IRB Administrative Assistants, IRB Administrative Coordinators, IRB Administrators, and senior members of IRB staff. All staff members are charged with reviewing the work presented to them and identifying errors and omissions. Corrections are made as they are identified in order to ensure an accurate record of the IRB’s reviews.

In addition to quality control on an individual basis, data integrity reports are conducted on a regular basis. These reports capture errors made in Penn ERA with data entry. Each report is disseminated to the IRB Administrative Support and Coordinator staff (where applicable) to make the data entry corrections in PennERA.

There are four data integrity reports that are populated on a weekly basis and sent out every Monday morning via email by the PennERA Support Team. (eraadmin@orsperdbprl01.isc-seo.upenn.edu).

1. HS Missing Data report
   a. captures issues where letters are not uploaded, Board names are missing, sponsor is not assigned, etc.). These are assigned to IRB Administrative Support and Coordinator staff (where applicable) to address the issues with protocols.
2. HS Invalid Data report
   a. captures data entry errors made to the protocols in Penn ERA (i.e. status of a submission, agenda dates are in the past, meeting dates are scheduled before agenda dates, etc.). These are assigned to IRB Administrative Support and Coordinator staff (where applicable) to address the issues with protocol

3. HS Aging Data report
   a. is assigned to IRB Assistant Staff Member to address the issues with protocols that should have been previously closed out or expired (depending on the review outcome).

4. HS Inconsistent Data report
   a. captures items that have identified principal investigator changes. This report is referred to ISC given that the parameters set for this report require updates.

QC/QI Process Development

If new quality control needs are identified, new quality improvement and quality control processes may be developed in order to better ensure accurate and timely completion of IRB activities. While needs may be identified by any member of the IRB staff, the QC development processes may not move forward without approval from the Director. The Director will charge the QI team leader and other members of IRB staff to develop new processes. These processes will then be presented to the IRB staff before implementation. Processes will be piloted and revised as needed. If the process is determined to be effective and appropriate, the Director will determine if it should be made permanent. Once the process is made permanent, IRB policy documents will be reviewed to determine if any revisions are required in response to the new process.

Quality Improvement For Compliance and Effectiveness of IRB and HRPP

Periodically the IRB will conduct activities to assess or improve internal compliance and effectiveness of the IRB and, on a wider scale, the Penn Human Research Protections Program. The Associate Director with the assistance of the Special Projects Leader will identify projects to assess the effectiveness of the IRB and HRPP as well as compliance with internal IRB SOP, Institutional policy, or other research regulations, laws and statutes. Depending on the nature of the project, other IRB Administrator or Coordinator staff may be required to contribute to the development and execution of these projects.

A comprehensive list of these projects is maintained on the shared G Drive in the HRPP QI folder. The spreadsheet is used to track project status, staff members involved, and a timeline for implementation, evaluation, obtaining feedback, monitoring implementation of changes that are needed as a result of the activity, overall success of activity as needed.

For each project a comprehensive report is generated to capture details of the background of the project, description of the QI activity, results, and next steps. The finalized reports are also stored on the shared G Drive in the HRPP QI folder for future reference in driving QI activities.

The progress and results of these projects may be reported to the VPR at monthly director meetings, Compliance Leads Committees established by the University and Penn Medicine, and bi-annual meetings with senior leadership within the Office of Audit, Compliance, and Privacy (OACP).
OVERVIEW
This section details the processes in place to ensure that paper and digital documents are stored and maintained appropriately. IRB Protocol files are stored in either the IRB file room or the electronic submission system (HS-ERA). In addition, most of the other documents related to IRB processes are stored digitally on the IRB’s servers (G: Drive).

PROCEDURES

**Paper File Maintenance**
Some active studies were created prior to the existence of the Human Subjects Electronic Research Application (HS-ERA) system. These studies are documented with physical paper files. After a review has been completed and a decision letter has been sent to the study team, the letter drafter is responsible for adding the decision to the physical file.

The letter drafter reviews the submission to make sure that all appropriate documents are included. The letter drafter then places the submission and a copy of the determination letter in the file. The letter drafter reviews the protocol folder in its entirety to ensure that all previous reviews are arranged in chronological order and the file is organized according to IRB standards.

Once the file is updated, the assistant returns it to the file room. The file room is arranged in alphabetical order based on the last name of the Principal Investigator and then by protocol number. As of 2017, existing paper files for Non-Human subjects research and Prime / Umbrella Grant determinations have been archived according to University policy. Going forward, all submissions for these types of applications will either be received electronically or scanned and saved as a digital file within PennERA for record keeping.

The Records Specialist is responsible for file room maintenance and will regularly check the file room in order to ensure that it is organized correctly. In addition, when a study is closed the records specialist will archive the file. The Records Specialist updates PennERA to detail where in the archives the file will be stored. In the event that a file must be recalled from archives, the Records Specialist will have it returned to the IRB.

**Electronic File Maintenance**
The electronic submission system (HS-ERA) also serves as the protocol file. Once a submission is received by the IRB, the submission becomes a permanent part of the electronic protocol file regardless of whether it is approved or returned for revision.

After a review has been completed, the IRB administrator and assistant will review the electronic submission while generating and forwarding the decision letter. If any documents were submitted via email, the study team will be instructed to formally submit them in the future via modification or continuing review so they may appear as part of the electronic record.

The electronic system serves as its own archives. IRB staff can locate closed and expired protocols by searching HS-ERA in the same manner they search for current protocols.

**Documentation of Agendas and Minutes**
All finalized versions of the Agendas and Minutes for IRB meetings are stored in both PennERA and the G: Drive in designated folders. The IRB administrator and assistant are responsible for ensuring that these documents are stored in both locations. Additional information about Agenda and Minutes generation is available in other sections of the GDO.
Member Documents
Membership letters and current curriculum vitae for each ember are stored on the G: Drive in designated folders. The IRB Administrator and Roster Assistant are responsible for ensuring that these documents are stored properly. Additional information about documentation of IRB Membership is available in other sections of the GDO.

IRB Rosters
Rosters are reviewed on a monthly basis and updated as necessary. The Roster for each IRB for each month is stored on the G: Drive in designated folders. The IRB Administrator and Administrative Assistant are responsible for ensuring that these documents are stored properly.

Standard Operating Policies Documentation
The current version of the Standard Operating Policies is published on the IRB website. The current version and previous version of the Policies is stored on the G: Drive in designated folder. The IRB Director is responsible for ensuring that these documents are stored properly. Additional information regarding policy and procedures maintenance is available in other sections of the GDO.
OVERVIEW
The IRB is required to keep its Federal wide Assurance and its rosters registered and up to date with the Office of Human Research Protections. The processes for completing these tasks are described below.

PROCEDURES
The IRB Director works with the Institutional Official to ensure that the University’s Federalwide Assurance (FWA) remains current. The FWA must be renewed every 5 years. However, if changes are made to the legal name of the Institution, the Human Protections Administrator/IRB Director, or the Signatory Official at any time during the 5 year approval period, the FWA must be updated within 90 days. The Director will complete the steps necessary for submitting timely FWA renewal requests. The Director may designate support staff to assist in this process.

The Director is also responsible for updating the membership rosters filed with the Office of Human Research Protections (OHRP). The Director will regularly review the OHRP rosters and update them according to the rosters stored on PennERA and the G: Drive. The Director may designate support staff to assist in this process.

All assurances and IRB registration information are publicly available on the IRB Website (www.irb.upenn.edu)
OVERVIEW
Research subjects are encouraged to contact the IRB if they would like to speak to someone who is not a member of the study team. Subjects may have questions about their rights as a research subject or would like to register a complaint about a research study. This section describes how the IRB receives and responds to these communications with subjects.

PROCEDURES

Receipt of Question/Complaint via Telephone:

The Informed Consent Form template includes a telephone number that subjects can use to call the IRB if they have questions, concerns or complaints regarding their participation in a research study. The template language informs subjects that it is recommended that they first speak with the principal investigator for the study but if a member of the study team cannot be reached or subjects want to speak to someone who is not working on the study, then they should contact the IRB at 215-898-2614. Regardless of whether a study team opts to use the IRB templates, the IRB requires the addition of IRB telephone contact information to the finalized consent versions.

The IRB Front Desk Assistant is responsible for answering any call to the subject complaint number during normal office hours. If a Front Desk Assistant is unable to pick up the line, the call is automatically forwarded to the IRB Assistant Director. If the Assistant Director is unable to answer the line, the subject will be directed to the Assistant Director’s voicemail.

Whoever first receives the call should identify whether it is a subject complaint. The call should then be forwarded to the Assistant Director. If the Assistant Director is unavailable, the Associate Director or Director should take the call. If they are not available, the caller should be asked to leave a voicemail message for the Assistant Director.

Receipt of Question/Complaint via Inter-Office Communication:

Research subject questions or complaints may be forwarded to the IRB by research teams or other IRB offices. Any IRB staff member who receives a notification of a potential subject question or complaint should forward that communication to the IRB Assistant Director. If the Assistant Director is unavailable, the messages should be forwarded to the Associate Director or Director.

The Assistant Director should review the information provided in order to assess the complaint and determine the most appropriate course of action. If additional information is needed, the Assistant Director may reach out the office that forwarded the message or to the individual subject in order to discuss the matter.

Responding to Subject Question or Complaint

The IRB Assistant Director receives the complaint or questions from the subject. The Assistant Director takes informal notes during the conversation. The Assistant Director focuses on obtaining information about the question or complaint, information about the study the subject was enrolled on (name of principal investigator, study title, etc.), and the name of the member of the study team with whom the subject has been interacting.

The Assistant Director should obtain the name and contact information for the subject who is raising the concern. The Assistant Director should also confirm whether or not the subject is lodging the complaint anonymously or if the subjects’ name can be used when inquiring with the study team or others. Finally, the Assistant Director should give the subject a time frame for when the subject should expect to receive a resolution or update on the status of the complaint. If the complaint is provided by an outside office and contains all necessary information, the Assistant Director...
may choose to not contact the subject directly at this point in time. If the complaint is complicated or the investigation is expected to require a significant amount of time, the Assistant Director should contact the subject to ensure that the subject is aware of the timeline and has the Assistant Director’s contact information for any questions.

The Assistant Director drafts a summary of the notes taken during the conversation. The Assistant Director should take care to securely handle the information obtained from the subject. Discussions and email correspondence about the complaint should refrain from using identifiable information unless necessary and the subject has given the IRB permission to use identifiable information.

The Assistant Director contacts the study team to obtain any additional necessary information from them about the study. The Assistant Director then discusses the concern with the study team and together they attempt to resolve the issue. The Assistant Director provides recommendations for the resolution of this complaint and for taking steps to ensure similar complaints are not raised in the future. If additional entities at Penn or at other institutions need to be contacted, either the Assistant Director or the study team should contact the appropriate entities. At any point during this time, the Assistant Director may consult with the Associate Director and Director to determine the most appropriate course of action.

Once a plan for resolving the issue has been put in place, either the Assistant Director or the study team should contact the subject and inform them of the outcome. If the communication from the study team directly is determined to be the most appropriate course of action, then the Assistant Director may not communicate with the subject again and may consider the matter resolved. Depending on the nature of the concerns raised, the Assistant Director may ask for documentation of the study team’s contact with the subject. If the subject is unsatisfied with the result, additional steps can be taken to address the complaint.

In the event the study team is unwilling to take the steps needed to resolve the complaint and the subject is unwilling to accept the study team’s response, the Assistant Director may refer the complaint to the convened IRB for review. This complaint would be considered a reportable event and reviewed according to the Reportable Event Procedure.

The Assistant Director documents the process taken in response to the complaint. Once the complaint has been resolved, the notes and any supporting documentation are provided to the Director for filing. The Director maintains a subject complaint file for the IRB.
OVERVIEW

Community outreach should occur in an ongoing fashion and feedback provided from the research community in the surrounding area should be incorporated into research practices in order to improve subject understanding of what research entails and what participation in research means. The IRB website contains information for subjects about participation in research and some links to information pertaining to the role of a research subject.

Periodically, the community outreach efforts and information provided for the research community are assessed and any improvements/additions that can be made are incorporated. These assessments and any revisions/improvements made in response shall be announced via a memo on the IRB website for the research community and the Philadelphia area to view.

PROCEDURES

Assessments of ongoing community activities will occur to verify opportunities to reach out to the general public in the Philadelphia area and provide information/education about available research studies and the role of the research subject.

Annually, the IRB will solicit a report of all community outreach efforts conducted by members of the Penn research community. This will include reporting from investigators conducting community engagement and outreach to specific communities as a part of IRB approved protocols. Examples would include results of community consultations for protocols requesting exception from informed consent, targeted recruitment initiatives and field work in specific communities conducted to obtain input on study design and execution. These reports shall include any results of evaluations performed for these activities.

Annually the IRB will collate these efforts into one report for analysis. This annual report compiled by the IRB, which will also include additional community outreach specifically conducted by the HRPP, will be reviewed at the IRB Chairs meeting and will be assessed for determining what revisions/additions/deletions should be made to community outreach practices. The findings of the IRB Chairs will be reported back to all entities engaging in community outreach. Best practices will be developed in partnership with the research community and will then be shared with the community. These assessments and any revisions/improvements made in response shall be announced via a memo on the IRB website for the research community and the Philadelphia area to view.

The progress of these efforts will continually be monitored through the annual reporting and evaluation described above.

The IRB staff participating in community outreach activities is responsible for securing information about the community outreach activities of the research community and compiling them into the annual report for evaluation. Staff members may be selected to participate, based on their background or particular role at the IRB, or Staff members may volunteer to work on these efforts. The Associate Director considers proposals from the IRB staff, or the research community, and identifies which proposals may produce the most advantageous opportunities to reach the potential research community in the Philadelphia area based on the annual evaluations.
OVERVIEW

The IRB charges a review fee when conducting initial and ongoing reviews for industry sponsored protocols and applicable federally funded protocols. All members of the IRB staff are involved in assisting with the identification of research protocols that may be eligible for billing and invoicing. The steps taken by IRB staff for this process are described below.

PROCEDURES

The IRB staff members track protocols that are eligible for IRB fees. The various standardized worksheets for expedited screening of submissions include instruction for the screener to identify whether the protocol is Industry Sponsored or a multi-site study for which the Penn IRB serves as the IRB of record. In either situation an email is sent from the screener to the IRB Business Administrator regarding a potential billing scenario.

In addition to the expedited screening process, The IRB staff review items being prepared for convened agendas and identify any industry sponsored protocols, or multi-site protocols where Penn is serving as the central IRB that are undergoing initial and ongoing review. The IRB staff will send an email to the IRB Business Administrator to alert them of the potential billing scenarios.

Utilizing the email updates from the IRB staff regarding protocol submissions that may qualify for billing based on sponsorship, as well as an independent review of IRB agendas, The IRB Business Administrator reviews the contract to determine if it contains language related to IRB fees. The Billing Administrator also reviews the contract to ensure that the language related to IRB fees is correct and in line with the fees the IRB charges for initial and ongoing review.

The Billing Administrator shares this information with the IRB Billing Coordinator in the Office of the Vice Provost for Research. This list of protocols contains information related to the industry sponsor that should be billed. Any issues noted during this review are sent to the IRB Business Administrator for further review. The Billing Coordinator journals IRB fees from the different research departments.
OVERVIEW
Authority to sign documents is designated according to IRB policies. The Director is charged with regularly reviewing and amending individual staff member authorizations.

PROCEDURES
Authority to sign IRB documents is based on an individual staff member’s position, training and expertise. Staff responsibilities for signing documents often change after completion of probationary periods and at the time of promotion. The Director is to be kept apprised of staff members training and expertise and will revise staff’s signatory authority as appropriate. Signatory authority is documented by the Director.
OVERVIEW
In addition to the Human Subjects Electronic Research Application (HSERA), the IRB also maintains a separate informational and resource website – www.irb.upenn.edu. The IRB website is an important resource for the IRB staff and the research community. This section describes the variety of website content and the procedures for maintaining it.

INFORMATION & RESOURCES STORED ON THE IRB WEBSITE
- All submission forms related to ongoing research. The required forms for Continuing Review, Modification, Exception Requests etc... are stored for public download. The full list of required submission forms is described elsewhere within the GDO. These forms are stored on the “Forms and Templates” page as well as individual pages dedicated to “How to Submit” each submission type
- Step by step instructions for creating all types of submissions that the IRB reviews
- Template Consent forms for various types of research
- Template protocols for various types of research
- The most recent copy of the IRB SOPs and individual policy memos
- IRB Fee Schedule
- IRB Federalwide Assurance and IRB registration Information
- Guidance information and documents developed by the IRB staff to assist investigators with obtaining and maintaining IRB approval
- Resources for IRB members such as guidance documents and checklists to assist the review process
- A complete calendar of convened IRB meeting dates, times and locations
- Resources for in person training and education of the research community
- Complete IRB staff directory

Due to the submission process involving attached submission forms, the IRB website and its content must remain accessible at all times.

WEBSITE MAINTENANCE PROCEDURES
Access to revise and publish content to the IRB website requires a username and password for “backdoor” access. This Access Username and Password is kept by the IRB Administrative Manager and the Special Projects leader as well as the IRB Director. Access to revise the website may be granted to other members of the IRB staff along with extensive training for proper use of the web design interface. The Access Username and Password should never be shared with anyone outside the IRB unless express permission is granted by the IRB Director. A separate document with step by step instructions for basic website revisions is available on the IRB Shared G Drive.

In collaboration with the IRB Directors, via the various processes outlined throughout the GDO, the Special Projects leader and Administrative Manager work together to ensure the web content related to IRB procedures is up to date and accurate. Updates occur on a regular basis as needed. The content may be published as basic page content, attached documents stored for public download, or temporary news items.

For website structural design and functional elements, the IRB has contracted iFactory as a third party vendor of web development services. Only the Administrative Manager, Special Projects leader and IRB Business Administrator have access to request work orders from iFactory through the iFactory teamwork portal.

The website is hosted on the Penn Pantheon server, thus collaboration with Penn ISC is occasionally required to ensure proper access and functionality. Issues identified with server access and functionality should be submitted to ISC help / Hire IT via the ticket system.
OVERVIEW
In support of various collaborative functions of the IRB, the IRB staff is granted access to shared email inboxes to manage various approvals and requests. This section identifies each of those inboxes and describes various procedures for their maintenance.

IRB PO BOX
The IRB POBOX (irb@pobox.upenn.edu) is a general assistance email inbox. Investigators are encouraged to contact the IRB POBOX for help with general policy inquiries, status of reviews and clarification of approvals. This email address is posted on the front page of the IRB website as well as within the website directory under “Get Help By Topic”.

The IRB POBOX inbox is managed by the administrator level staff. Senior analysts will serve as backup when necessary. Management of the box is coordinated on a rotating daily schedule. Response times for emails received is dependent upon staff availability and complexity of the request. Below are best practices that should be followed:

• If the administrator managing the box doesn’t know how to answer the email request, the email should be triaged in a timely manner to appropriate IRB personnel within the office (e.g., senior analysts, directors, etc.).
• Emails that require follow up from other IRB staff (e.g., questions about the status of a review) should be forwarded in a timely manner to the relevant IRB staff member.
• Email requests for submission guidance should be directed to relevant website guidance, instructed to review that guidance, and then follow up with relevant staff with their specific questions.
• Emails should be responded to or forwarded to other IRB staff no later than 3 business days after the email has been received.
• After a message is forwarded, the email should be archived.
• Emails that have been responded to directly from the PO Box can be deleted from the POBOX.

HSERA HELP DESK
The HSERA Help desk (hsera_help@lists.upenn.edu) is a helpdesk specifically for technical issues related to utilizing the HSERA system. Investigators are encouraged to contact the help desk when encountering errors while filling out applications, missing or incorrect information within the application, and general assistance for completing the application. The email address is posted on the bottom of every page of the HSERA application as well as on the IRB website directory.

The HSERA helpdesk is managed by the IRB Technical Support Specialist with backup support from the Special Projects Leader and various administrative Coordinators. Emails received by the HSERA helpdesk may require forwarding to ISC for troubleshooting. Response times for emails received is dependent upon staff availability and complexity of the request.

PENN/CHOP AGREEMENTS INBOX
Due to the unique cooperative relationship between the University of Pennsylvania and the Children’s Hospital of Philadelphia, the respective IRBs frequently enter into Authorization Agreements for the oversight of research that involves both entities but only require single IRB review. The Penn CHOP agreements inbox provides the CHOP IRB with a direct line (outside of HSERA) to establish and manage Cooperative Agreements with the Penn IRB when CHOP will be serving as the IRB of Record.

New protocols for agreements as well as renewals and modifications to existing agreements are submitted to this inbox (pennchop@exchange.upenn.edu) . The CHOP IRB staff submit documents via email that are then processed by the IRB staff to establish records of active research projects at Penn which are overseen by the CHOP IRB. Specific details of these agreements and the procedures for implementation are described elsewhere within the GDO.
UNIT 1- IRB ORGANIZATIONAL OPERATIONS

1.9 Shared Inboxes

Generally the PennCHOP agreements box is managed by the IRB Associate Director with support from the Special Projects leader. Requests to the inbox may be forwarded to other members of the IRB staff for processing and documentation. Response times for emails received generally aligns with the deadlines for similar applications received via HSERA or paper submission.

ANCILLARY REVIEW INBOX

As the IRB is only one office within the Penn Human Subjects Protections Program, the Ancillary Review Inbox ([IRB-Ancillary@pobox.upenn.edu](mailto:IRB-Ancillary@pobox.upenn.edu)) has been set up in order to directly receive documentation of review outcomes (approval letters) from the other various Penn entities that review Human Research. This may include CTSRMC, RRSC, IBC, among others. The correspondences received in this inbox almost always include attachments that must be uploaded to various IRB systems such as HSERA or Penn ERA. These review results directly inform the IRB in their decision making on granting full or withheld approval to new and ongoing research projects. Additional information about Ancillary review is available in other sections of the GDO.

The Ancillary Review inbox is managed by IRB Administrative Support Staff members with back up from various IRB Administrative Assistants and Coordinators. Emails received via the Ancillary review inbox do not require outgoing responses. However, the documentation received should be uploaded to the appropriate protocol as soon as possible to facilitate ongoing IRB review.

CONTRACTS INBOX

IRB Review of industry sponsored research requires that the injury section of informed consent forms describing compensation from sponsors be reviewed by the IRB for consistency with the finalized contract. To facilitate this process, the Contracts Inbox ([IRB-Contracts@pobox.upenn.edu](mailto:IRB-Contracts@pobox.upenn.edu)) has been established as a direct line for the IRB to receive finalized contracts from ORS and the Clinical Trial Contracting Unit for review.

The Contracts inbox is generally managed by the IRB Administrative Coordinators. Contracts that are received are forwarded via email to the IRB Administrator for the board which performed the Initial review of the study. As IRB approval is contingent upon this process, Contracts must be forwarded for administrator review within 24 hours. This process results in either:

1. Request for revisions to the consent form to align with the contract OR
2. Drafting of an updated approval letter with a stamped copy of the consent forms.
OVERVIEW
The IRB has routinely conducted review of research by way of requiring application forms which must be completed by the study team and submitted along with basic study documents and materials. As the research landscape and, in turn, the HSERA application has developed and progressed, more specialized forms have been developed as necessary. This section serves as a complete list of existing submission forms that are expected to be either attached to HSERA to supplement the electronic application, or submitted in hard copy for those active studies which pre-date the electronic system.

Each form includes detailed instructions for study teams to follow in order to submit all of the necessary information for IRB consideration. IRB staff who perform screenings should take note of these instructions during the screening process in order to determine whether a submission is complete.

Please note that this list does not duplicate items within the list. Each form is included once in the most commonly used scenario. For example, a study may be modified after initial approval to request a HIPAA Waiver. However, for the purposes of this list, the Request for Waiver of HIPAA Authorization Form is only listed as a form for New Projects as that is the most common scenario when this form is received.

FORM AVAILABILITY
All application forms that are required to be submitted to the IRB are stored for public download on the IRB website (www.irb.upenn.edu) on the Forms and Templates page.

FORMS FOR SUBMITTING A NEW PROJECT (INITIAL REVIEW) – The following forms may be required when a new project will be submitted for IRB review:

- Human Subjects Research Determination Form
- Quality Improvement Project Application Form
- Devices in Research Form
- Drugs in Research Form
- Subpart B Form (Research involving Pregnancy/ Fetuses/Neonates)
- Subpart C Form (Research Involving Prisoners)
- Subpart D Form (Research Involving Children)
- Request for Waiver of HIPAA Authorization Form
- Anatomic Pathology Services Form
- Clinical Lab Services Form
- Transfusion Medicine Services Form
- Social Media Account Request Form

FORMS FOR ONGOING REVIEW OF RESEARCH – After a study is granted initial approval, the following forms may be required when new information is being submitted for IRB review:

- Modification Form
- Exception Request Form
- Reportable Event Form: Medical Event
- Reportable Event Form: Non-Medical Event
- Deviation Form
- Closure Form

FORMS FOR RENEWING RESEARCH – For studies that require renewal, the following forms may be necessary to submit a complete Continuing Review:
UNIT 1- IRB ORGANIZATIONAL OPERATIONS
1.10 Application Submission Forms

- Standard Continuing Review Form
- PI Compliance Assessment Form (PICA)**
- Prime Grant Continuing Review Form

**Please note that the completed PICA form is not submitted directly to the IRB. However, IRB staff should be familiar with its contents and instructions for use in the context of continuing review.

FORMS FOR COOPERATIVE REVIEW/RELIANCE REVIEW- For new, ongoing and renewal reviews of research where Penn serves as the IRB of record for multiple sites or is relying on another IRB, the following forms may be required:

- CHOP/Penn Cooperative Agreement Form
- Individual Investigator Agreement Form
- IRB Authorization Agreement Form
- Participating Site Addition Form
- Principal Investigator Assurance Form
- Protocol Supplement for Requests to Rely on an External IRB
- Schulman IRB Cover Page
- Single/Central IRB Continuing Review Form
- Relying Site Supplemental Continuing Review Form
OVERVIEW
The IRB has routinely conducted review of research by way of utilizing template checklists and worksheets which must be completed by the IRB Staff and Members to document the review. As the research landscape and, in turn, the HSERA application has developed and progressed, more specialized checklists and worksheets have been developed. This section serves as a list of existing checklists and worksheets that are expected to be attached to HSERA comments, (or provided in hard copy with the most recent study file for paper studies) in order to document the IRB review.

All IRB checklists and worksheets include specific instructions for appropriately completing the related review. The items in each checklist ensure the IRB is consistently considering and applying the criteria for approval as well as numerous administrative details related to conducting research at Penn. As these documents are routinely updated in an ongoing fashion, the templates for conducting reviews are not directly included with the GDO and are stored separately. The sections of the GDO relevant to conducting expedited and convened reviews will directly reference these checklists and worksheets. In addition to utilizing the GDO, IRB staff should refer to the most recent version of the checklist or worksheet to determine the required areas of assessment and appropriate documentation methods.

AVAILABILITY
All checklists and worksheets relevant to the IRB staff are available in blank template form on the IRB shared G drive - G:\IRB\**2019** STAFF resources quick access\Staff Screening Worksheets & Tools. The IRB staff is expected to utilize the most recent versions of each provided form at all times to ensure completeness and consistency of IRB review.

All checklists and worksheets that are relevant to IRB Members are available for public download on the IRB website (www.irb.upenn.edu) on the IRB Toolbox page.

**please note the folder name will be updated annually to display the current year**

FOR SCREENING NEW PROJECT (Initial) SUBMISSIONS – The following checklists and worksheets should be used to screen and prepare new projects for approval:

- Initial Exempt Checklist
- Initial Expedited checklist
- Initial Full board Checklist with Admin stip appendix
- Reliance Agreement Request Checklist
- Subpart B Worksheet (Research involving Pregnancy/ Fetuses/Neonates)
- Subpart C Worksheet (Research Involving Prisoners)
- Subpart D Worksheet (Research Involving Children)
- Drugs/Biologics Worksheet
- Devices Worksheet
- Department of Defense Checklist
- Department of Energy Checklist
- Department of Education Checklist
- Department of Justice Checklist
- Environmental Protection Agency Checklist

FOR SCREENING RENEWALS – For studies that require renewal, the following checklists should be used to screen and prepare for approval:

- Minimal Risk CR Checklist
- Greater than Minimal Risk CR Checklist
FOR SCREENING ONGOING REVIEW SUBMISSIONS— For non-renewal submissions received after the initial review, the following checklists should be used to screen and prepare for approval:

- Response to Stipulations Checklist
- Modification standard screening checklist
- Relying IRB Modification checklist
- Site Addition Modification Checklist
- Reportable Event / Deviation Checklist
- Closure Checklist

IRB MEMBER REVIEW FORMS- When an action requires convened review, the IRB members should be encouraged to utilize the most recent versions of the following worksheets to document their reviews and share notes with the IRB Chair and Board administrator in advance of the meeting:

- IRB Member Primary reviewer worksheet (For review of New Initial Submissions only)
- IRB Member Secondary Reviewer Guidance (For review of New Initial Submissions only)
- IRB Member Modification Review Worksheet
- IRB Member Continuing Review Worksheet
- IRB Member Pragmatic/Comparative Effectiveness Clinical Trial Ethical Review Tool
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OVERVIEW
This section details the processes for training new staff members on the policies and procedures of the IRB.

PROCEDURES

The Associate Director is responsible for developing and implementing the new staff education and training program. The program is customized to new staff members and their strengths, weaknesses and previous experience. While customizable, the program will always involve the completion of CITI human subjects’ protections course, a 4 to 6 month probationary period as defined by the University, and a review session at the completion of the probationary period. The Associate Director may designate additional experienced IRB staff to assist with the training program. Updates from the Associate Director to the Director will be provided throughout the training period.

Upon completion of the probationary period, the trainer(s) and Associate Director will meet with the trainee and review progress made during the probationary period. If necessary, the probationary period may be extended in order to provide new staff with additional training and skill development. If the trainer(s) and Associate Director determine that the probationary period can end, the meeting will focus on ongoing skill development and goal setting for the remainder of the University’s performance period. Although the University defined probation period is utilized as a benchmark for initial training, completion of job training for most IRB positions typically requires one year or more of routine exposure to various aspects of each position.

TRAINER EXPECTATIONS

The Associate Director is responsible for developing and implementing new staff education and training program. Implementation routinely requires the involvement of other experienced IRB staff members to provide daily support and mentorship throughout the probationary period and beyond as necessary. To simplify the training process for the trainee, the training team is typically limited to one or two individuals in addition to the Associate Director. As training progresses and the workflow becomes more complex, more staff members may be brought onto the training team for support.

The educational approach focuses on mastering basic skills before advancing to more complex responsibilities. Trainees will then move on to more complex assignments after basic skills are mastered. Finally, multiple tasks will begin to be assigned to trainees in order to develop skills related to multi-tasking and priority setting. The trainers will monitor assignments to trainees and provide guidance and feedback throughout the process in order to ensure that assignments are completed in a timely and appropriate manner.

As part of training new staff, the following expectations apply:

- Trainers will provide updates to the Associate Director and Director as needed. If appropriate, the trainer(s) may suggest revisions or extensions to the education and training plan set by the Associate Director in order to better tailor the program to the trainee.
- Trainers will ensure that the trainee has completed basic human subjects’ protections training course available online through the CITI program. Anyone who has not previously completed the course are asked to complete the IRB member course. The biomedical research course or social/behavioral research course may also be accepted if previously completed as these courses are supplemented by additional orientation materials.
- Trainers will be expected to have an individual level plan for incorporating the training program into their daily workflow and communicate regularly with the Associate Director to manage their workload in favor of the training program.
- Trainers will be expected to communicate regularly with the trainee about appropriate timelines for assignment completion and feedback in context of their own daily work assignments.
UNIT 2 - IRB STAFFING & BOARD MEMBERSHIP
2.1 New Staff Education and Training

- Trainers will provide copies of the IRB SOP and GDO for trainee reference. It should be made clear to all trainees that these documents are available for reference for day to day activities. Trainers should also utilize the GDO, SOP, or other specific guidance documents in the training program wherever possible for consistency and point out which sections are relevant for the current training expectations.

- Trainers will acclimate the trainee to the layout of the office and provide guidance regarding location of necessary materials for their job function including:
  - Location and layout of the file room. How to locate a study within the file room and appropriate handling of research files
  - Office supplies
  - Training team offices/cubicles to facilitate communication
  - Appropriate break areas and Conference room amenities

- Trainers will provide a basic introductory tutorial of the PennERA and HSERA systems

- At the appropriate time, trainers will provide a tutorial for utilizing the shared G;Drive that all IRB staff and Directors utilize for electronic file sharing including:
  - IRB staff resources for review materials (Checklists and worksheets)
  - Electronic letters which require PDF signature
  - IRB Board folders for convened meeting management of agendas, checklists etc...

- The trainer(s) will provide more in depth review of policies and procedures as trainees move through probation and training period.

- Training programs typically begin with basic approval letter assignments to develop skills in extracting information from HSERA and inputting data into PennERA. Trainers are expected to check each completed letter against the HSERA submission for content, check for errors in the letter itself and also check PennERA data entry for errors. Each letter assignment should be used as an opportunity to provide feedback and corrections. Trainers will continue the letter checking process until such a time that the trainee has successfully completed enough letters with no mistakes to signal they no longer require additional coaching in this area and may complete letter assignments on their own.

- For positions involving expedited screening of research submissions, a checking system similar to that of the letter generation process should be utilized. Trainees should be coached daily on finding information in HSERA, proper use of screening checklists, documentation in HSERA and PennERA until they demonstrate they are ready to screen submissions on their own.

- For positions involving administration or coordination of a convened Board, trainers should provide routine guidance for screening convened submissions, preparing agendas, taking and preparing minutes, management of information and documents on the G; Drive, and interactions with Board members both existing and prospective.

TRAINEE EXPECTATIONS
Throughout the training period, Trainees will be systematically introduced to new assignments and concepts. Due to the complexity of IRB operations, trainees may be required to learn and demonstrate multiple new skills on a daily basis. The training team will provide immediate coaching on a daily basis for each skill until proficiency is demonstrated. Once proficiency is demonstrated, the training team will introduce new skills that require immediate coaching and follow up less frequently about skills that have already been demonstrated.

- All trainees must review existing IRB SOP, GDO, IRB website guidance, and forms to familiarize and raise pertinent questions.
UNIT 2 - IRB STAFFING & BOARD MEMBERSHIP
2.1 New Staff Education and Training

• All Trainees must complete basic CITI training for Human Subjects Protections
• All Trainees must demonstrate proficiency in navigating the HSERA system
• All Trainees must demonstrate proficiency in accurate data entry within PennERA
• All trainees must demonstrate strong assignment management skills using the tools provided (HSERA Assignment Queue, Outlook inboxes and calendars)
• All trainees must demonstrate proficiency in managing appropriate email correspondence with the research community
• Depending on the position being trained for, trainees may be expected to further develop:
  o exemplary letter drafting skills utilizing HSERA and PennERA
  o comprehensive knowledge of expedited screening requirements and processes
  o comprehensive knowledge of convened screening requirements and processes related to board management
• Trainees are expected to routinely communicate with the training team regarding their needs, concerns and questions.
OVERVIEW
IRB staff members receive education and training on a regular basis. This section details the typical methods used to develop staff education throughout the year.

PROCEDURES

Staff Meetings
Weekly staff meetings may have an educational or training presentation. These presentations may be led by any IRB staff member, Director, or invited guests. Topics related to educational needs of the IRB staff are covered. Topics and presenters are selected by the Directors and Senior IRB administrators. Minutes are also taken at staff meetings for the benefit of absent staff.

Individual Trainings
Any staff member may determine when individual staff members may benefit from one-on-one training on specific topics or procedures. Training sessions seek to develop new skills and expertise in an area related to human subjects’ protections or IRB operations. Training sessions may also be utilized to address issues with skillset or ability to complete tasks which may require additional re-training. The Directors may assign a specific mentor to the IRB staff that will provide support and guidance during the training. The mentor and Directors will determine when the IRB staff member has developed the necessary competency to complete the tasks with minimal supervision.

External Conferences/Seminars
Staff members are encouraged to expand their knowledge base and subject-matter expertise by attending national and regional conferences that cover topic areas pertinent to human subjects’ protections. Staff members at all levels are afforded an opportunity to attend external educational opportunities. Permission for staff to attend conferences is granted by the Director. To ensure collective benefit from staff participation in these external activities, staff afforded an opportunity to attend are required to present the lessons learned from their participation/attendance at a staff meeting.
OVERVIEW
This section details the process for assessing performance of IRB staff. Staff assessments are completed at least annually and additional assessments may be conducted as needed.

PROCEDURES

Annual Performance Reviews
IRB staff members undergo a yearly performance review pursuant to University Policy. The Director establishes a timeline for completion of the performance review and informs the staff of their responsibilities and obligations during this process.

Each IRB staff member writes a self-assessment according to University Policies. The self-assessment details competencies demonstrated over the previous years, individual goals that have been completed, and upcoming goals for the following year. Once completed, this self-assessment is provided to the staff members’ supervisor.

Supervising staff review the self-assessment and provide a review of the staff member’s performance over the past year. The supervisor(s) also comments on goals set by the supervisee and may provide additional goals for the coming year. The performance assessment is then provided to the Director for Review and Comment.

After receiving the Director’s review, the supervisor(s) meet(s) in person with supervisee and discusses the performance assessment. The supervisee then signs the performance assessment. The signed performance assessment is then provided to the Director for filing according to University Policy.

Performance Improvement Plans
Throughout the year, supervising IRB staff may need to document identified needed areas for improvement of staff members they oversee. Supervising staff will consult with the appropriate senior staff member when problems are identified and determine if a performance improvement plan is warranted. If necessary, staff will implement a plan in accordance with University Policies. Documentation of staff’s performance through the improvement plan will be generated by the Supervisor. The documentation will then be provided to the Director who will store the documentation according to University Policies. If performance fails to meet expectations established in the performance plan, additional warning and disciplinary actions may be necessary. These actions will be documented and be made accessible to HR as applicable per University Policies.

Informal Assessments
IRB staff members are encouraged to track and log any informal documentation related to their performance. This documentation is often received from colleagues, supervisors, and the research community. Staff members are also encouraged to share this information with supervisors and the Director in order to generate a comprehensive picture of staff strengths and weaknesses.
OVERVIEW
The Board Member recruitment process is flexible and Senior Staff tailor this process to the needs of the IRB and the potential members expressing interest in the IRB. This section discusses the general processes involved in identifying and recruiting new Board members.

PROCEDURES
The overall Board Membership recruitment strategy is set by the Director in consultation with the Vice Provost for Research. Strategies are based on the specific needs of the Boards at various points in time. Potential members are approached by senior members and staff of the IRB. More junior members and the IRB staff are encouraged to discuss participation with potential members and then refer individuals to the appropriate staff member.

After a potential member expresses interest in serving on a Board, the member is invited to observe an IRB meeting. Senior IRB staff set up a convenient time for the member to observe. The staff member informs the IRB administrator and assistant for that Board that a guest will be attending the meeting. The senior staff asks the potential member to provide a resume or CV for consideration.

At the meeting, the potential member first signs a Guest Confidentiality form. The potential member then receives a copy of the meeting agenda and observes the meeting. After the meeting is over, the potential member will sit down with the Senior IRB Staff member to discuss interest in serving on a Board. Other Board members and IRB staff may be invited into that discussion.

If the potential member expresses a desire to join the IRB, they will be provided with the board schedules so they may choose based on scheduling and availability.

The Director/Associate Director receives a copy of the potential members CV and a description of the Boards and membership slots that are available at that time. The Director/Associate Director considers the expertise of the member and the needs of the IRB when deciding whether to approve a term for the Member and the findings of the assessment are discussed with the IRB Chair, as applicable.

If the member is accepted, the Senior Staff member informs the Administrator for the Board who adds the member to the roster. Training for the new member is scheduled with the appropriate IRB personnel at which time onboarding member documents including confidentiality and conflict of interest statements should be completed.

If the member is not accepted, the Senior Staff informs the potential member of the reason why he or she could not be accepted at this time.
OVERVIEW
The Perelman School of Medicine offers a degree program for students whose projects and career goals align translational science. As part of this curriculum, one required core course is related to Scientific and Ethical Conduct. In this course students will learn the foundational principles of scientific and ethical conduct of research, complete directed experience in evaluating these principles through IRB membership and ultimately be able to apply them to their own work. The directed experience will include membership for six months on an Institutional Review Board (IRB) at either the University of Pennsylvania or the Children’s Hospital of Philadelphia. This membership experience will expose students to real issues, considerations, and solutions in human subject’s research and study design. This section explains IRB staff responsibilities for facilitating MTR student membership and successful completion of this course.

PROCEDURES
IRB Directors are directly involved with the MTR program and determine which Board each student will be assigned to. Depending on the number of students, one or more may be assigned to any particular Board. Once Board assignments have been made at the director level, IRB Administrators and Coordinators are provided with contact information for their assigned students. IRB Administrators and Coordinators are ultimately responsible for:

- Ensuring the appropriate Board Membership documents are completed
- Confirming plans for each student to observe one IRB meeting at their Board prior to being given review assignments
- Confirming plans for each student to attend 6 meetings (in addition to their observation meeting) at which they will be assigned at least one review. Completion of reviews at 6 meetings is required to complete the course.
- Providing review and guidance materials to facilitate the review process
- Ensuring review notes and comments are sent to the Board Chair and IRB Administrator in advance of each meeting
- Communicating with IRB directors about MTR student attendance or review obstacles when appropriate

Upon completion of the MTR program, MTR students may opt to end their IRB membership, or stay on their assigned Board as a full time member or an alternate.
OVERVIEW
The following procedures are implemented by IRB staff for creating Board membership rosters, maintaining the Board membership rosters, and ensuring the PennERA system provides the most current Board membership information to date.

PROCEDURES

Adding New Members to Rosters
After a new Board Member has been accepted for a Board, the Senior IRB Staffer who worked on the recruitment project notifies the IRB Administrator for the Board the member is joining and notifies the IRB administrator to draft the IRB membership letter. The Senior Staffer provides both administrators with a copy of the Member’s resume, information on the role the Member will serve, and the length of the Member’s term.

The IRB Administrator updates PennERA to include the new member. The administrator navigates to the Human Subjects Administration – Board Administration fields and selects the appropriate roster. The member information is updated to include the new member and indicate the length of membership term. The IRB Administrator also updates the Roster Spreadsheet for the Board. This roster is stored on the G: Drive and is updated to include the new member and detail the length of the member’s term.

The Administrator then works with Senior Staff to help the new member through the new member training process.

Renewing Existing Membership Terms
IRB membership is assessed in an ongoing fashion on an individual member basis. Unless otherwise informed of a termination of membership, memberships are automatically renewed.

IRB Rosters will be reviewed periodically to identify expiring or inactive members. The IRB staff contacts both the Board Chair and the Director and requests their determination on whether the member’s term should be renewed or expired. If the Chair and Director agree that the member should be asked to continue to serve for another term, the IRB Administrator asks the member if they are willing to serve for another term.

Once the member’s response has been received, the IRB Administrator informs the Assistant if a membership renewal or a thank you for your service letter should be generated. The IRB Administrator than updates the rosters in PennERA and the G: Drive to reflect the new or expiring term.

Terminating Memberships
If a Board Member resigns from the IRB or a decision is made to terminate a Board Member’s term prior to its expiration, the IRB Administrator is responsible for ensuring that the Director, and IRB Chair are all informed of termination. The IRB Administrator then updates the rosters in PennERA and the G: Drive to reflect the terminated term. The IRB administrator informs the IRB Assistant that a thank you for your service letter should be drafted for the member.

Membership Letter Generation
Each IRB member is provided with a membership letter drafted by the appropriate IRB staff member. The letter should outline the membership action that is occurring and the effective date. These letters are converted into PDFs and sent to the IRB Administrator. The IRB Administrator reviews the letters for accuracy and completeness. The letters are then forwarded to the Director for review and signature. The Director reviews and signs the IRB membership letters. Signed letters are then returned to the Administrator.
UNIT 2 - IRB STAFFING & BOARD MEMBERSHIP
2.6 Board Roster Maintenance
The Board Administrator and/or Assistant then upload all signed letters for storage on the G: Drive. New membership and renewal letters are combined with Confidentiality and Conflict of Interest Statements and sent to the Board Members. Members are asked to sign the statements and give them to the IRB administrator at the next board meeting. Signed statements are stored on the G: Drive along with the signed membership letters.

DOCUMENTATION OF ROSTER MAINTENANCE

As a result of the processes noted above, each IRB Board Administrator should:
- Maintain and post the most recent board roster to the designated folder on the G: drive monthly.
- Utilize the Program Tools for Board Administration in PennERA to assign access to their board members and ensure their membership is accurately reflected on IRB documentation of review activities
- Finalize each set of IRB Minutes with a complete representation of the board roster on page 1 indicating which members attended the meeting documented therein.
2.7 New Member Training

OVERVIEW
The IRB has a variety of educational initiatives designed to orient new members to IRB review processes and the regulations governing human subjects’ research. These activities are detailed below.

PROCEDURES
The senior IRB staffer involved in recruitment of the member and the IRB administrator for the Board the member is joining, work together to make sure that the member completes the initial orientation process. Before new members are assigned primary or secondary reviews for agenda items, new members are required to observe at least one convened IRB meeting, including one meeting of the Board to which the member has been assigned.

In addition, IRB staff will provide new members with orientation materials including Amdur and Bankert’s IRB member handbook and details regarding the Board’s roster and meeting schedule. New members are also introduced to the digital archive for member resources that includes copies of the IRB’s reviewer forms/checklists as well as additional ethical and regulatory guidance materials for later reference.

All new members undergo a new member training session prior to serving as a member of a convened IRB. The new member training is led by Senior IRB staff with assistance from IRB administrators and provides instruction first on the core mission of the IRB, including applicable ethical considerations, regulatory requirements, and the criteria for IRB approval. Associated determinations based on the satisfaction (or lack of satisfaction) of the criteria for approval are described for each type of submission. Instructions regarding the expected work of members prior to and during the convened meeting are outlined thoroughly, both for their own reviews as well as for those not assigned to them. Finally, procedural guidance for how to perform these reviews – including navigation of the electronic application system, review of IRB agendas and minutes, and use of reviewer guidance materials and checklists – are all discussed with the member with particular emphasis on the anticipated types of review they will conduct based on their expertise and. The instructing staff member also leaves time for adequate questions from the member and receives the signed confidentiality agreement from the member as well, which is documented by the Board’s administrator.

At the time of the first direct review assignments, new members are also afforded an opportunity to walk through any questions/concerns they have with a member of the IRB staff to ensure all applicable criteria for approval have been appropriately considered by the member in the process of the review.

All IRB members are notified of the request to complete a basic human subjects’ protections course available online through the CITI program at www.citiprogram.org. Members who have not previously completed the course (if they are not researchers at Penn) are asked to complete the IRB member course. The biomedical research course or social/behavioral research course may also be accepted if previously completed and applicable to the types of reviews that will be conducted by the Board to which the member has been assigned. The IRB administrator is responsible for informing members of the CITI training requirements and ensuring that required training has been completed.

The IRB provides opportunities for new IRB members to collaborate with seasoned members while they gain experience. Some new members may be paired with a specific seasoned IRB member on the same Board when determined to be appropriate. All new members are asked to share questions, comments and review notes regarding their review assignments with the Board Chair, IRB Administrator, and secondary reviewer in advance of the meetings. IRB administrators assign reviews according to member expertise, background, and IRB experience level.
OVERVIEW
IRB Board Members are provided initial and ongoing training in the review and conduct of human subjects’ protections. IRB staff has the responsibility to create and present ongoing training through informative presentations monthly.

PROCEDURES
The Senior Staff designates and informs an IRB Staff Member to construct an IRB Board Member ongoing training presentation for an upcoming IRB Board Member meeting. The Senior Administrator and designated IRB staff work together to select a topic pertaining to human subjects’ protections and design a training presentation.

The IRB Staff Member must complete a draft of the training presentation in the time given by the Senior Staff Member. The IRB Staff Member prepares a draft of the presentation by utilizing institutional and software resources (e.g. library services and PowerPoint) while communicating to the Senior Staff about any issues or questions should they arise. In addition, the IRB Staff Member includes a brief summary about the ongoing training to be included in the finalized minutes. The IRB Staff Member sends the ongoing training and its summary to the Senior Staff Member for review. The Senior Staff reviews the IRB Staff Member’s draft training presentation. Any revisions and/or concerns are communicated to the IRB Staff Member. The IRB Staff Member makes any necessary revisions to the training presentation. The IRB Staff Member presents the training at an IRB Administrators meeting to ensure each board administrator is prepared and able to present the same training at their respective board meeting.

The IRB Staff Member addresses any necessary revisions to the ongoing training that were voiced at the IRB Administrators meeting. Upon finalization of any revisions, the IRB Staff Member emails the ongoing training presentation, any supplemental documents, and the brief summary for the minutes to all IRB Administrators. Copies of the trainings are also stored on the G: Drive and posted on the IRB website Member Toolbox for future reference.

Each IRB Administrator receives the ongoing training documents and includes the ongoing training in the agenda email to the Board Members. The ongoing training summary is saved for later inclusion into the finalized minutes. The IRB Administrator presents the ongoing training at the appropriate IRB convened meeting either before or after the agenda depending on time constraints. A summary of the ongoing training is included in the finalized minutes.
OVERVIEW
IRB Board membership is reviewed and assessed on an annual basis through a self-assessment completed by members and a general review completed by IRB staff. This process is done to ensure that Board members are appropriately trained and that Board Rosters consist of members who are able to make meaningful contributions to human subjects’ protections at Penn.

PROCEDURES

IRB Member Self-Assessment
On a yearly basis, the IRB asks its members to complete a self-assessment survey based on their level of experience with the Board: one version for new members (with the Board for less than one year) and for experienced members (with the Board for one year or more). These surveys are usually released in the beginning of the summer term and remain open for one month for members to complete at their convenience. The IRB administrator conducts a training session before the release on the purpose of the surveys and how to complete them in the manner that will give the IRB the most useful information possible. The IRB administrator will email the corresponding links to the surveys to all members of the Board, along with the deadline for their completion.

The surveys and training materials are drafted by Senior Staff and presented to the Administrators at a staff meeting. The surveys are revised on an annual basis to best suit the needs of the IRB but typically includes information on member training, level of comfort with various review activities, and experience conducting specific types of IRB review (subpart determinations, waiver of consent requests, etc.), both prior to the meeting and through meeting discussion. IRB Chairs also receive a third, more extensive survey regarding their experiences as Chair and the strengths or areas of improvement for the Board for the year to come.

Completed surveys are stored in a departmental, password-protected account via a third-part approved for use by the institution. Reminder emails are sent to any members who have not completed the survey.

IRB Board Review
After the deadline has passed, all received survey data is compiled and reviewed by senior IRB Staff and the IRB administrator. Trends in data across member responses – including but not limited to regarding review type, comfort level, requested trainings, and even goals for personal improvement as a member – are all compiled and discussed amongst the IRB senior staff prior to being presented to the remainder of the IRB Chairs. In addition to this broader analysis, IRB staff also determines if individual member training is needed and if targeted training to the Board as a whole would be valuable.

Expiration Review
When a Board member’s term is due to expire, the IRB administrator asks the Chair and Director to consider whether the member should be asked to return for another term. The Chair and Director review the members’ expertise and contributions to the Board over the previous term. The Chair and Director also consider whether the member would benefit from additional training. The results of this review are given to the IRB administrator. If further training or actions are warranted, the administrator consults with the Associate Director and Director to determine the best course of action.

Membership Feedback
After IRB leadership has met to discuss the results of the member self-assessments, the findings are presented to the IRB chairs at the next available IRB Chairs Meeting. During that meeting, the Chairs are consulted on the recruitment and training goals of the Boards and specific members if needed. This feedback is then incorporated into the self-assessment findings.
2.9 Member Assessments
The feedback provided by IRB leadership and the chairs are summarized and presented to the Board members. The presentation is given at convened IRB meetings and takes the place of that month’s member training presentation. If individualized feedback or training is appropriate for a member, it will be provided by either the Chair or IRB staff via a one on one discussion.
# UNIT 3

## IRB REGULATORY OPERATIONS

### 3.1 Application of ICH GCP (E6) Guidance

### 3.2 HRPP Ancillary Committee Review Procedures
- HSERA Bio Page Summary
- EHRS – RRSC – RDRC Reviews
- IBC Review
- CAMRIS Review
- CACTIS Requirements
- CTSRMC Review
- HRAC Review
- HSRAC Review
- CHPS/CTRC Resources

### 3.3 Contract Review for Industry Sponsored Studies

### 3.4 Office of Clinical Research (OCR) Joint Procedures

### 3.5 Review of Protocols Administering Drugs and Devices

### 3.6 International Research

### 3.7 Waivers of HIPAA Authorization & Data Use Agreements

### 3.8 Conflicts of Interest and CISC Review
- IRB Staff Conflicts
- IRB Member & Consultant Conflicts
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- Institutional/Organizational Conflicts

### 3.9 Vulnerable Populations Review
- Subpart B (research with pregnant women, neonates, or fetuses)
- Subpart C (research with prisoners)
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- Other Populations vulnerable to undue influence or coercion

### 3.10 OHRP Certification Letters for Prisoner Research

### 3.11 NIH Certificates of Confidentiality

### 3.12 Requests for GWAS Certifications

### 3.13 Requests for Permission to Use Data

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OVERVIEW
ICG-GCP Is International Conference on Harmonization - Good Clinical Practice. Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and wellbeing of trial subjects are protected; consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

The objective of this ICH GCP guidance is to provide a unified standard for the European Union (EU), Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

The guidance was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries, and the World Health Organization (WHO).

This guidance should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities.

The principles established in this guidance may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.

APPLICATION OF ICH-GCP (E6):

As ICH-GCP (E6) provides supplemental guidance in addition to the FDA and DHHS regulations, ICH-GCP (E6) will not be followed to completion for most research conducted at the institution. For a complete overview of which parts of ICH-GCP (E6) the University of Penn IRB is not compliant with, the ICH-GCP compliance letter, available on the IRB website, should be referenced.

For research submissions that require alignment with ICH-GCP (E6), the IRB will work the Principal Investigator (PI)/Research Team to meet the additional elements outlined in ICH-GCP (E6).

When screening an initial submission, if it is requested in the submission that the study be aligned with ICH-GCP (E6), the IRB Administrator will bring this request to the attention of a member of the senior team. The request to align with ICH-GCP (E6) will be considered and if appropriate for the particular submission, the IRB Senior Staff will work the IRB Administrator and the research team to employ any revisions needed to align the submission with ICH-GCP (E6) guidance.
OVERVIEW
Penn has several entities that review human subjects’ research protocols. This group is referred to as the Human Research Protections Program or HRPP. These Ancillary Entities have jurisdiction over research protocols that involve certain procedures. The IRB can grant approval of research protocols before they are reviewed by the ancillary entity, but subjects are not permitted to be enrolled until review has occurred. This section details the processes in place to ensure that the IRB accounts for Ancillary review during the IRB review process.

HSERA BIO PAGE FOR INDICATING NEED FOR ANCILLARY REVIEW
The HSERA online application BIO/HRPP page contains multiple questions related to the Penn ancillary committees’ review requirements. When screening a protocol, the screener should be aware that if any questions on this page are answered “YES” then the study is subject to review by the related specific ancillary committees.

If the IRB Administrator believes that any question is answered incorrectly, the IRB Administrator should obtain confirmation from the study team regarding whether a specific committee review is necessary. Once screening is complete and all responses have been confirmed as accurate, the agenda notes should be updated to indicate which committees must review the protocol. If the study is approved by the IRB prior to approval by the ancillary committees, the approval letter template language confirms that the study team cannot enroll subjects until all relevant approvals have been obtained. The stamped informed consent form should not be provided until all conditions are met.

A brief breakdown of the questions on the BIO/HRPP page and their purpose is provided below for reference:

- Clinical trial question-YES sends ping to Office of Clinical Research.
- Investigator initiated question-YES sends ping to Office of Clinical Research.
- Drugs and device, receipt storage and management question- If Yes for IDS Letter must include note for study team to alert IDS of IRB approval prior to starting enrollment
- Radiation exposure- YES Sends Ping to Environmental Health and Radiation Safety/ Radiation Research Safety Committee/Radioactive Drug Research Committee
- Gene transfer- YES sends ping to IBC and triggers HRAC review assessment
- CT Scan question- YES requires CACTIS review and approved risk language
- MRI question- YES requires CAMRIS review and approved risk language
- Storage of drug or device in Operating Room YES sends ping to surgical services
- Cancer related research question- YES sends ping to CTSRMC
- CTRC Resources question – YES sends Ping to CHPS/CTRC. Also requires separate CTRC application through HSERA

EHRS - RADIATION RESEARCH SAFETY COMMITTEE/RADIOACTIVE DRUG RESEARCH COMMITTEE
The Penn Environmental Health and Radiation Safety Committee oversees both the Radiation Research Safety Committee (RRSC) and the Radioactive Drug Research Committee (RDRC). Both sub-committees review Human Research Protocols in conjunction with approval from the IRB.

**RRSC** - The Radiation Research Safety Committee (RRSC) reviews most research protocols involving ionizing radiation exposure to subjects solely because of participation in the research protocol. The RRSC also reviews research protocols for affiliated institutions, such as the Children’s Hospital of Philadelphia, Pennsylvania Hospital and Penn Presbyterian Medical Center. RRSC review and approval is needed for human research protocols involving the administration of ionizing radiation to humans solely because of participation in a research study (with the exception of protocols that are reviewed by the RDRC). When making a determination about the necessity of RRSC approval of a protocol, it is useful to ask the following question: “Would the individual receive the radiation dose even if they were not enrolled in the research protocol?” If the answer is “yes”, then RRSC review and approval is not required.
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3.2 HRPP Ancillary Review Procedures

Only protocols that have been submitted via the HS ERA system (Penn) or eIRB system (CHOP) may be reviewed by the Committee. Notification of a protocol’s need for review by the Committee and its availability are made when the PI indicates that radiation is used solely for research purposes on the HS ERA or eIRB online application.

For protocols requiring RRSC review, IRB Approval may be granted prior to RRSC review however, any requirements from RRSC review must be incorporated via modification prior to beginning subject enrollment.

**RDRC** - In certain situations, human research protocols involving the use of radiopharmaceuticals may be reviewed by the Radioactive Drug Research Committee (RDRC). However, the criteria for reviewing protocols under the RDRC is very specifically defined by the FDA regulations in 21 CFR 361.1.

To be eligible for review by the RDRC under 21 CFR 361.1, a protocol must:

- Involve certain radioactive compounds generally recognized as safe and effective;
- Be designed to use the radioactive compound to obtain basic information regarding the metabolism of the compound or regarding human physiology, pathophysiology, or biochemistry;
- Not be intended for immediate therapeutic or diagnostic use;
- Not propose to determine the safety and effectiveness of the drug (i.e., to carry out a clinical trial);
- Not be designed as part of the routine medical management of patients with a particular condition.

The RDRC also reviews research protocols for affiliated institutions, such as the Children’s Hospital of Philadelphia, Pennsylvania Hospital and Penn Presbyterian Medical Center.

For protocols requiring RDRC review, IRB Approval may be granted prior to RDRC review however, any requirements from RDRC review must be incorporated via modification prior to beginning subject enrollment.

**INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)**

The IBC is responsible for providing review and oversight to ensure that all forms of research conducted at the University of Pennsylvania and within the University of Pennsylvania Health System are in compliance with the NIH Guidelines and all of the University’s policies for use of the following:

- recombinant or synthetic DNA (r·s·DNA)
- infectious agents,
- human and non-human primate materials (including established cell lines),
- select agents,
- biosafety level 3 (BSL-3) research
- and human gene transfer

For protocols requiring IBC review, IRB Approval cannot be granted until IBC approval is granted. Once the screener of a submission confirms that the study involves any of the above listed products the following must be completed:

- Confirm that the IBC review question in HSERAs is answered correctly
- Agenda notes should clearly indicate that IBC review is required before IRB approval can be granted
- An administrative stipulation detailing the requirement for IBC review should be included in the IRB determination letter

Once notification of IBC approval is received, the submission can be placed for approval and a stamped consent form may be released, assuming all other IRB stipulations are met.
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3.2 HRPP Ancillary Review Procedures

CENTER FOR MAGNETIC RESONANCE IMAGING & SPECTROSCOPY (CAMRIS)
The overall mission of CAMRIS is to provide oversight in the responsible use and application of Magnetic Resonance Imaging in research. In order to ensure safety and to communicate proper risk/benefit information to subjects who may consent to MRI research within CAMRIS, they require that certain risk information be included in each consent form. The required clauses are broken up into two categories: those studies that are using experimental sequences and/or coils, and those that are using standard sequences and/or coils. CAMRIS also provides important safety information regarding the use of Gadolinium based contrast agents. CAMRIS conducts independent reviews of research protocols in order to provide guidance to research teams regarding MRI policy, procedures and subject safety. Research teams may be required to submit a CAMRIS application in addition to identifying use of MRI in the HSERA application.

Research that requires CAMRIS review may be approved by the IRB prior to receiving CAMRIS approval, however enrollment of subjects may not begin until CAMRIS approval is granted and CAMRIS approved risk language is inserted into the consent form. The standard language for MRI scans is publicly available on the CAMRIS website.

CENTER FOR ADVANCED COMPUTED TOMOGRAPHY IMAGING SERVICES (CACTIS)
The purpose of the Center for Advanced Computed Tomography Imaging Services (CACTIS) is to facilitate productive research within the guidelines set forth by the Institutional Review Board (IRB) of the University of Pennsylvania for human study subjects. Under the direction of the Chair, Dr. Harold Litt, the CACTIS committee reviews proposed research requests and makes decisions and recommendations accordingly. CACTIS will review proposed research protocols involving humans, animals, phantoms or specimens prior to initiation of the project. This review process has two major goals:

• To ensure all research performed within the CT facilities complies with CACTIS policy, University policy, and Federal Regulations
• To analyze proposed research requirements for safety and feasibility, and to identify the resources needed to carry out each research protocol (including personnel, software, hardware and scan time)

CACTIS also determines whether the CT risk information in the informed consent form is appropriate for the proposed research. Research that requires CACTIS review may be approved by the IRB prior to receiving CACTIS approval, however enrollment of subjects may not begin until CACTIS approved risk language is inserted into the consent form. The standard language for CT scans is publicly available on the CACTIS website.

CLINICAL TRIALS SCIENTIFIC REVIEW AND MONITORING COMMITTEE (CTSRMC) REVIEW PROCEDURES
The Cancer Center’s Clinical Trials Scientific Review and Monitoring Committee (CTSRMC) are tasked with reviewing and tracking all cancer related research, with few exceptions. IRB approval of cancer related research protocols can occur prior to CTSRMC review, but subjects are not permitted to be enrolled until CTSRMC review has occurred or been determined to be not applicable. It is also recommended that CTSRMC review take place prior to IRB review, for investigator initiated protocols, to prevent significant scientific questions from affecting the ethical review.

When screening a protocol, the IRB Administrator should confirm that the study is considered cancer related research. Detailed information about the types of studies the CTSRMC is required to review and track is available at http://www.ctsrmc.org/submitting_a_protocol.php (Pennkey and Password required for access)

Once the screener of a submission confirms that the study qualifies for CTSRMC review the following must be completed:

• The HSERA online application cancer related research question should be answered correctly according to CTSRMC requirements outlined at the link location provided above.
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3.2 HRPP Ancillary Review Procedures

- The agenda notes should be updated to indicate that CTSRMC review is required.
- An administrative stipulation detailing the requirements for CTSRMC review should be added to the determination letter if the study has not yet been reviewed by the CTSRMC.

If CTSRMC review occurs before IRB review, the IRB may be forwarded a copy of the CTSRMC decision letter for review of any stipulations that may impact the IRB’s approval criteria. Prior to the convened meeting the IRB Administrator will contact the study team to request for a response to any stipulation that could impact the IRB’s approval criteria and upload the CTSRMC decision letter to the HSERA application in order to allow IRB Members access to this letter. The IRB Administrator will share any responses from the study team with the IRB Members to be considered during the convened meeting. If a stipulation impacts the IRB’s approval criteria and is not addressed prior to IRB review, the IRB decision letter will include a stipulation similar to the CTSRMC’s stipulation.

Once notification of CTSRMC approval is received, the submission can be placed for approval and a stamped consent form may be released, assuming all other IRB stipulations are met.

HUMAN RESEARCH ADVISORY COMMITTEE (HRAC) REVIEW PROCEDURES

The mission of the Human Research Advisory Committee (HRAC) is to advise the Vice Provost for Research on the potential institutional impact of issues related individual research protocols (specifically use of gene transfer), and research programs when appropriate. HRAC may also advise on issues related to overall institutional approach to the execution of human research and interests of the institution that could potentially impact the conduct of any specific human subjects’ research protocol or the integrity of the Human Research Protections Program (HRPP).

The IRB Staff, as part of the completeness check process for initial submissions, modifications or requests for continuing review, may identify through the screening of the HSERA application that HRAC review is required.

HRAC review may be required under the following conditions:

- HSERA Application or Protocol documentation indicates use of Gene Transfer
- Testing, development or evaluation of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania. Intellectual property conflicts may be reported to the IRB by a variety of mechanisms including but not limited to:
  o Directly through the IRB application through identification of intellectual property interests or interests of a senior departmental leader
  o Through the review of individual financial interests reported to the Office of the Vice Provost for Research
  o Via the Penn Center for Innovation

If the screener of a submission suspects that HRAC review is required the following must be completed:

- Notification to the IRB Associate Director
- Notification to HRAC
- Confirm that the Gene Transfer or Intellectual Property question in HSERA is answered correctly

The IRB Associate Director will act as a liaison between the IRB and the HRAC to determine if formal review is required. Once the determination is made, the Director informs the IRB Administrator. Either the Director or the IRB Administrator will contact the study team to inform them of the requirement for HRAC review. If HRAC review is found to be required the following must be completed:

- Agenda notes should clearly indicate that HRAC review is required prior to IRB approval
- An administrative stipulation detailing the requirements for HRAC review should be added to the determination letter.
Once notification of HRAC approval is received, the submission can be placed for approval and a stamped consent form may be released assuming all other IRB stipulations are met.

**HUMAN STEM CELL RESEARCH ADVISORY COMMITTEE (HSRAC) REVIEW PROCEDURES**

The Human Stem Cell Research Advisory Committee (HSRAC) is charged with review of certain research protocols that involve human embryonic and human induced pluripotent stem cells. This section details the processes in place to ensure that the IRB accounts for HSRAC review during the review process.

The IRB Staff, as part of the completeness check process for initial submissions, modifications or requests for continuing review, may identify through the screening of the HSERA application that HSRAC review is required. If the study is determined to meet the definition of human subjects’ research, IRB approval cannot be granted until HSRAC committee review and approval has been granted or the HSRAC Administrator has confirmed that HSRAC review is not required.

Once the screener of a submission confirms that the research involves human embryonic or human induced pluripotent stem cells the following must be completed:

- Notification to the IRB Associate Director
- Notification to HSRAC
- PennERA and Agenda notes should clearly indicate that HSRAC review is required prior to IRB approval
- An administrative stipulation detailing the requirements for HSRAC review should be added to the determination letter.

Once notification of HSRAC approval is received, the submission can be placed for approval and a stamped consent form may be released assuming all other IRB stipulations are met.

Often, stem cell research protocols submitted to the IRB will not meet the definition of human subjects’ research. Regardless of the level of IRB review required for the protocol, the IRB Associate Director should be engaged and HSRAC should be notified of any study involving human embryonic and/or human induced pluripotent stem cells. Final determinations for IRB review should be on hold until HSRAC has either confirmed that their formal review is not required, or provided a formal review determination about the research.

**CHPS/CTRC RESOURCES**

The Center for Human Phenomic Science (CHPS) [formerly the CTRC-Clinical and Translational Research Center] provides resources, environment, operations, and training to support and promote high-quality clinical and translational research by qualified investigators.

Within CHPS, the Study Design and Biostatistics (SDAB) Core works closely with existing resources to provide targeted study design and biostatistics support to ITMAT/CTSA investigators. The Core serves as a direct provider of services, including protocol review, study design, proposal development, and performance of simple to potentially substantial complex analyses. SDAB integrates the support available with the HUP and CHOP Center for Human Phenomic Science (CHPSs), the expertise and resources of faculty in the Center for Clinical Epidemiology and Biostatistics / Department of Biostatistics and Epidemiology (CCEB/DBE), and the Biostatistics Analysis Center (BAC).

CHPS provides resources for design, setup, conduct and close-out/publish phases of clinical research. CHPS offers a facilitator service at no charge to help design and implement clinical research studies within the CHPS at the time of grant application to enhance the research design and to communicate details regarding CHPS resources and costs. For funded applications, a CHPS facilitator can meet with investigators and their coordinators to help obtain CHPS and IRB protocol approval. After approval, a CHPS facilitator will continue to work with the study team to initiate the protocol.
CHPS also provides resources for investigational product accountability and destruction, database quality control and finalization, subject un-blinding and follow up as well as coordination with the IRB and other Penn Ancillary review entities throughout the duration of the research.

Investigators must apply for CHPS support through HSERA by filling out a CTRC request. IRB approval of research may be granted prior to approval from CHPS, however any changes requested by CHPS must be incorporated via HSERA modification or initial response prior to beginning enrollment.
OVERVIEW
The IRB regularly grants approval of industry-sponsored protocols prior to the finalization of the contract for that protocol. The negotiated contract impacts the consent form for the study because the contract describes the circumstances where coverage for research related injury will be provided by the sponsor. The IRB has put in place processes to ensure that the consent form appropriately details what will occur if a subject is injured. This section details those processes.

GENERAL ARRANGEMENT FOR CONTRACT CHECKS
Contract checks may be conducted at the time of initial screening for an industry-sponsored study if there is a master agreement on file, or there is a protocol-specific contract that has been finalized. A contract check may also result from a modification if an industry sponsor is changed or added.

If no master agreement is on file and/or the protocol-specific contract is pending at the time of screening, the contract checks will occur outside of the system. In these instances, the IRB Contract PO BOX will forward the finalized protocol-specific contract via email to the appropriate IRB staff for checking; there will be no specific submission associated with the check.

MASTER AGREEMENTS AND PROTOCOL-SPECIFIC CORPORATE CONTRACTS
If the study is industry-sponsored and no protocol-specific contract has been forwarded to the IRB staff to date, the IRB staff should verify whether there is a master agreement on file for the sponsor. These documents can be found in the Master Agreement folder in Penn BOX. If available, these agreements can be used to conduct a preliminary check of the injury language in the consent form(s) prior to receipt of the protocol-specific contract, if applicable.

If a master agreement is not on file, the IRB staff should conduct the check with the protocol-specific contract, once received. As noted above, protocol-specific contracts will be forwarded to the appropriate IRB staff member for checking from the IRB Contract PO BOX once fully executed/finalized. Given this, the contract check may not occur until after the initial review of the study has taken place.

PROCEDURES FOR CONTRACT CHECKING
The IRB staff should locate the subject injury section of the master agreement or corporate contract. This is usually found in the “Subject Injury” or “Indemnification” section. Once located, the IRB staff should review this section to verify the instances when subject injuries will/will not be covered by the sponsor.

Next, the IRB staff should locate the injury language section of the consent form(s) and review for consistency. Please note that there may be instances where the same injury language is used across multiple consent forms for the same study. In these instances, there may be more than one consent form that warrants checking.

In general, the injury language in the consent form(s) should be written in lay terms for subjects. Additionally, this section should clearly inform subjects when injuries will/will not be covered by the sponsor.

One revision that is commonly requested by IRB staff is the removal of provisions that indicate subject injuries will not be covered if study directions are not followed, if this plan is not supported by the finalized contract. Any provisions that appear to waive subject rights, or include conflicting coverage language, should also be removed. Additionally, if the contract indicates that subject injuries directly related to participation will be covered by the sponsor, this information should be included in the consent form(s) for subjects if not currently indicated.

PROCESS TO FOLLOW IF NO MASTER AGREEMENT OR PROTOCOL-SPECIFIC CONTRACT EXISTS AT TIME OF SCREENING
If no master agreement or protocol-specific contract is available at the time of screening, the IRB staff should update the summary page of PennERA to indicate that the study is industry-sponsored and that the corporate contract is pending.
Additionally, the standard corporate contract pending administrative stipulation note should be included in the final letter. The templates for these notes can be found in either the Administrative Stipulations Appendix or the Letter Language Templates document—both are located on the G-Drive.

If a contract is pending for an industry-sponsored study, please note that stamped consent form(s) should not be released.

**PROCESS TO FOLLOW IF REVISIONS ARE NOT REQUIRED AS A RESULT OF CONTRACT CHECK**

If the contract check is performed and the IRB staff determines that no revisions to the consent form(s) are required, the IRB staff should update the summary page of PennERA to indicate that the check is complete, and no revisions are needed. It is recommended that staff name or initials and date be included with this information for reference purposes.

The study status will determine the other steps, if applicable, that will be needed to complete this process:

- **STUDY STATUS OF APPROVED CONTRACT PENDING:**
  If the study is otherwise approved pending the contract check, the contract check complete/no revisions needed note should be added to the letter and the applicable consent form(s) should be stamped.

- **STUDY STATUS OF WITHHELD OR TABELED:**
  PennERA should be updated as noted, but no further action is required. The consent form(s) should not be stamped.

- **STUDY STATUS OF PENDING IRB REVIEW:**
  If the study is in pending status (e.g. the initial application is pending review by the full board), an administrative contract check complete/no revisions needed note should be added to the agenda notes/final letter. However, reference to the release of the stamp consent form(s) in the template note should be removed. The consent form(s) should not be stamped until full approval of the study has been granted.

**PROCESS TO FOLLOW IF REVISIONS ARE REQUIRED AS A RESULT OF CONTRACT CHECK**

If the contract check is performed and the IRB staff determines that revisions are needed, the IRB staff should update the summary page of PennERA to indicate that the check was completed, and revisions are required. It is recommended that staff initials, and date be included with this information for reference purposes.

If the check was completed outside of the system (i.e., IRB Contracts PO Box forwarded the contract to the IRB staff via email for checking) and there is no pending submission, the IRB staff should reach out to the study team and principal investigator via email to inform them that the contract check for the protocol was conducted and updates are needed. In this email, the IRB staff should detail the changes that are required and request that a modification be submitted with the revisions. If the study is electronic, a copy of this correspondence to the study team should be uploaded to comments section of the most recent HS-ERA submission for internal tracking purposes.

If the check was completed as part of the initial screening for a full-board study, an administrative note with the required revisions should be included in the agenda notes/final letter. The standard contract check notes may be used as starting point for this purpose but will need to be updated on a case-by-case basis.

**DRAFTING CONTRACT CHECK LETTERS**

There are 2 different scenarios for drafting approval letters once a contract check has been completed and the consent forms are ready to be approved.
Scenario 1:
• The study has been granted initial approval, but the stamped consent was withheld from stamping pending contract review, AND
• The contract review performed outside the HS ERA system determined no revisions to the consent form are required therefore no modification will be submitted to formally process the contract approval.

If you are assigned to generate this type of contract approval letter, please follow these steps:

1. Update the status of the PennERA summary page from “Approved contract pending” to “Approved”
2. Create a new IRB review record in PennERA under the “post review” section of the original study approval record (so that we don’t run the risk of replacing the previous approval letter with the new version for record keeping purposes. This will also help to track review of the contract)
3. Set the radial button to the new “post review” record created as the determining review
4. Set the review decision for the determining review record as “approved” and the review category as “administrative”, with the reviewer set as the person in the office who made the final determination to approve the contract ICF
5. Under the “Communications” header of the determining review record, build a new Initial Approval letter and send to the attachments to create a placeholder to upload your new letter. Be sure to include the word Contract or CTA in your file name
6. Update the Word Version of the original approval letter. Add a revised date, remove the contract pending language and replace with the language shown below:

   “Please Note: The IRB has received the finalized contract for this study and conducted a review of the injury language section of the informed consent document. No revisions are requested to the injury language section at this time, therefore a stamped consent has been provided.”

Then PDF the letter, attach and stamp the approved versions of the consent forms, obtain signature if required, forward to the study team, and upload to HSERA/PennERA.

Reminder: The approval from and to dates on the updated approval letter should not be changed.

Reminder: The “approved to” date for the consent stamp should align with the approved to date in the letter. The “approval from” date for the consent stamp should reflect the date the contract review was completed by the IRB administrator assigned to do the contract review (so the approval on date will be different on the letter and the consent form - i.e. letter will reflect the date the study was approved and the consent stamp will reflect the date the consent form was approved)

Scenario 2:
The study has been granted initial approval, but the stamped consent was withheld from stamping pending contract review, AND a modification will be submitted to formally process the contract approval (usually due to the requirement for changes to the consent form,) please follow these steps:

1. Draft a modification approval letter per usual process
2. Include this note in the letter:
   “Please Note: The IRB has received the finalized contract for this study and conducted a review of the injury language section of the informed consent document. No revisions are requested to the injury language section at this time, therefore a stamped consent has been provided.”
3. Update the status of the PennERA summary page from “Approved contract pending” to “Approved”
OVERVIEW
The Penn IRB and the Office of Clinical Research conduct joint procedures to ensure research compliance within the Perelman School of Medicine. This section outlines the various collaborative measures that the IRB staff are expected to be familiar with to support these joint efforts.

OCR RESEARCH COMPLIANCE AUDIT PROCEDURES

The Office of Clinical Research (OCR) Compliance Unit is responsible for the conduct of risk-based routine and non-routine for cause compliance reviews of clinical trials conducted in the Perelman School of Medicine (PSOM). Routine compliance reviews are conducted on all PSOM or PSOM investigator held Investigational New Drug (IND) Application, Investigational Device Exemption (IDE) or comparable international regulatory filing. Specific procedures are outlined in PSOM SOP 200 (Compliance Reviews) A copy of this SOP is available on the shared drive: G:\IRB\OCR Audit Tracking

The OCR Compliance Unit communicates audit findings in the form of a Compliance Assessment Report (CAR). Findings that are relevant to human subjects’ protections are shared with the IRB via a shared Penn Box folder: https://upenn.app.box.com/folder/8216787293. The OCR Compliance Unit notifies the IRB Senior Administrators via email when a CAR report has been placed in the shared folder.

Senior administrators review CAR reports. The senior administrator reviews the CAR and adds comments to the CAR. The CAR with comments is sent to the Director and Associate Director for their review and concurrence. The CAR with comments is uploaded to the Penn Box folder.

An email is sent to the study team with the IRB’s feedback on the shared findings in the form of an email. The compliance reviewers are bcc’d on the email.

Study teams are expected to respond to compliance findings by way of the OCR Compliance team. Study teams are not expected to respond to audit findings by way of the IRB. However, study teams should report any findings that meet the criteria of a reportable event or deviation to the IRB per normal reporting requirements (submitting events in an expedited manner or at continuing review as necessary). Any events reported in an expedited manner will be assessed. If determined necessary upon screening, such events will be referred to the convened board for assessments of an unanticipated problem, or serious and/or continual non-compliance.

The CAR with IRB comments should be uploaded into the shared Penn Box folder. The OCR Audit Report Review Tracker should be updated to document the review took place. This is available on the shared drive: G:\IRB\OCR Audit Tracking.
OVERVIEW

Research involving the use of drugs and devices may require FDA review and approval via an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application. However, in certain circumstances, application to the FDA for approval is not required. This is the case for planned research activities that qualify for an IND exemption, studies in which the use of the device is exempt from IDE regulations, and studies that involve the use of non-significant risk investigational devices (NSR). For non-significant risk device determinations, the IRB may act as a surrogate of the FDA to confirm that the criteria are met.

Additional definitions and background information related to drugs and devices review is available in the following GDO Appendices:
- APP1- Drug Related Definitions And Background Information
- APP2- Device Related Definitions And Background Information
- APP3- Identifying Sponsors, Funders, & Collaborators In INDs/IDEs

PROCEDURES

During the pre-review of the submission, the Screener determines if an IND / IDE exemption or NSR determination is required or is being requested by following the steps below.

A. Screening Protocols Administering Drugs or Drug Products (biologics, cosmetics, food, food additives, vitamins, & supplements)
   1. During the screening process, the screener should identify all drug products being administered for research purposes on the study by reviewing the HSERA application and all submitted documents.
   2. The screener should review the following sections for accuracy and consistency between the application and the study documents. These are the application/document sections that are likely to reflect the administration of a drug product.

   HSERA
   - HRPP Page, Clinical Trial
   - HRPP Page, Investigator Initiated Trial
   - HRPP Page, Drugs or Devices
   - HRPP Page, Drug, Herbal Product or Other Chemical Element Management
   - HRPP Page, Processing of Material
   - HRPP Page, In-House Manufacturing of Materials
   - HRPP Page, Gene Transfer
   - HRPP Page, Protocol Interventions
   - Procedures Page, Procedures
   - Risks/ Benefit Page, Potential Study Risks

   Protocol
   - Investigational Products
   - Study Intervention

   Consent Form
   - What am I being asked to do?
   - What are the possible risks or discomforts?

   If the screener notices inconsistencies among the sections, the screener should request corrections be made.
3. The screener should document all of the products by completing the most up to date version of the Drug Screening Checklist when the research procedures involve the administration of biologics, drugs, cosmetics, food, food additives, vitamins, and supplements.

4. The Screener should follow the directions in the Drug Screening Checklist regarding the following:
   a. What information / notes should be added to Penn ERA summary and drug pages,
   b. What documentation is required (e.g., package insert or IB) to be uploaded in HSERA,
   c. What information should be requested from study teams,
   d. What should be corrected in HSERA and study documents

5. The screener should send any stipulations or queries to the study team as needed, either by returning the submission or sending an email to the study team.

6. The Drug Screening Checklist will guide the screener in determining whether an IND exemption determination needs to be made. The Screener should follow the directions on the form regarding whether the IRB should make the exemption determination, or if this should be referred to another internal entity.
   a. If the study risks appear to be minimal (per a review of the procedures and risks), the Director and/or the executive MD chair can confirm the study is IND exempt and qualifies for review under expedited category 1
   b. If the study risks appear to be greater than minimal (per a review of the procedures and risks), the study cannot qualify for review under expedited category 1. The study should be referred for convened board review.

7. If the study has an IND, the screener should attempt to identify whether a regulatory sponsor has been identified. The screener should use the Sponsor Guidance Document to delineate between Sponsors, Funders, and Collaborators. The screener should review the following sections for accuracy and consistency between the application and the study documents.

   **HSERA**
   - **Sponsor page** Funding Sponsor should reflect the funder
   - **Sponsor page** Regulatory Sponsor should reflect the IND sponsor, if it’s an entity
   - **Sponsor page** IND Sponsor should reflect the IND sponsor, if it’s a Penn Faculty.

   **PennERA**
   - **Overview or Pending Issue that May Impact Future Reviews**: If IND Exempt: Include a note that states this, who did the exemption, and the date of the letter (if done by another Penn internal entity)
   - **Penn IND Holder**: Should be checked when the University holds the IND. HSERA Sponsor page, Regulatory Sponsor will state University of Pennsylvania
   - **IND Holder**: Should list the IND Sponsor when it is any other person or entity than Penn.
   - **IND/IDE Number**: Should list the IND number
   - **Investigator Initiated Clinical Trial**: Should be checked when Penn Faculty is the IND Sponsor
   - **Drugs Page**: Should list all drugs being administered for research purposes

**B. Screening Protocols Administering Devices (e.g., implants, diagnostic devices, in vitro diagnostics, lab tests, assays, genetic testing, etc.)**

1. During the screening process, the screener should identify all devices being administered for research purposes on the study by reviewing the HSERA application and all submitted documents.

2. The screener should review the following sections for accuracy and consistency between the application and the study documents. These are the application/document sections that are likely to reflect the administration of a device.
UNIT 3 – IRB REGULATORY OPERATIONS
3.5 Review of Protocols Administering Drugs and Devices

**HSERA**
- HRPP Page, Clinical Trial
- HRPP Page, Investigator Initiated Trial
- HRPP Page, Drugs or Devices
- HRPP Page, IDE Review
- HRPP Page, Research Device Management
- HRPP Page, In-House Manufacturing of Materials
- HRPP Page, Protocol Interventions
- Procedures Page, Procedures
- Risks/ Benefit Page, Potential Study Risks

**Protocol**
- Investigational Products
- Study Intervention

**Consent Form**
- What am I being asked to do?
- What are the possible risks or discomforts?

If the sections are inconsistent or incorrect, the screener should request corrections be made.

3. The screener should document all of the products by completing the most up to date version of the Device Screening Checklist when the research procedures involve research devices, medical devices, and commercially available devices. The name of the device should be identified. If it is not, the study team should identify the name of the device.
   a. The only exception to this requirement is when the study clearly meets the criteria for expedited category 4 and medical devices at the hospital are being used. In this case, it’s evident that the devices are cleared or approved and thus qualify for review under category 4.

4. The Screener should follow the directions in the Device Screening Checklist regarding the following:
   a. What information / notes should be added to Penn ERA summary page and devices page,
   b. What documentation is required (e.g., device manual or instructions for use) to be uploaded in HSERA,
   c. What information should be requested from study teams,
   d. What should be correct in HSERA and study documents

5. The screener should send any stipulations or queries to the study team as needed, either by returning the submission or sending an email in advance of the convened meeting.

6. By following the Device Screening Checklist, the screener should determine the following to the best of his/her ability. The screener should require the submission of the Research with Devices form before attempting these determinations, unless the submission clearly delineates the information.
   a. If the device is being used as a medical device on the protocol,
   b. If the device is the subject of the investigation [if the purpose of the study is to test the safety or effectiveness of the device(s)]
   c. If the study qualifies for an IDE exemption (see number 7 below for more details on this). [If assistance is needed with the above determinations, the screener should consult with senior staff/director, OR refer the team to OCR Sponsor Support Unit.]
   d. If a device risk determination must be made by the convened board (see number 8 below for more details on this).
Applications and forms from the study team should clearly delineate rationale for an exemption or risk determination. If sufficient rationale is not provided, the IRB administrator should request additional information from the study team.

7. The Screener should follow the directions on the Device Screening Checklist regarding whether the IRB should make an exemption determination, or if this should be referred to another internal entity.
   a. If the study risks appear to be minimal (per a review of the procedures and risks), the Director and/or an MD chair can confirm the study is IDE exempt and qualifies for review under expedited category 1.
   b. If the study risks appear to be greater than minimal (per a review of the procedures and risks), the study cannot qualify for review under expedited category 1. The study should be referred for convened board review. If the convened IRB grants an IDE exemption or defers to FDA, the minutes and letter should document the determination.

8. If the study requires a risk determination OR the study already has an IDE number:
   a. Convened board review is required. A note should be added to the agenda notes informing the Board that a risk determination is required.
   b. The screener should attempt to identify whether a regulatory sponsor has been identified. The screener should use the Sponsor Guidance Document to delineate between Sponsors, Funders, and Collaborators. The screener should review the following sections for accuracy and consistency between the application and the study documents.

   **HSERA**
   • **Sponsor page, Funding Sponsor** should reflect the funder
   • **Sponsor page, Regulatory Sponsor** should reflect the NSR or SR IDE sponsor, if it’s an entity
   • **Sponsor page, IND Sponsor** should reflect the NSR or SR IDE sponsor, if it’s a Penn Faculty.

   **PennERA**
   • **Overview or Pending Issue that May Impact Future Reviews**: If IDE Exemption: Include a note that states this, who did the exemption, and the date of the letter (if done by another Penn internal entity)
   • **Penn IND Holder**: Should be checked when the University holds the IDE. HSERA Sponsor page, Regulatory Sponsor will state University of Pennsylvania
   • **IND Holder**: Should list the IDE Sponsor when it is any other person or entity than Penn.
   • **IND/IDE Number**: Should list the IDE number if it’s an SR device that has an FDA IDE number, OR state that it is an NSR IDE
   • **Investigator Initiated Clinical Trial**: Should be checked when Penn Faculty is the NSR or SR IDE Sponsor
   • **Devices Page**: Should list all investigational devices being administered for research purposes

**C. Convened Review of Protocols Administering Drug Products and/or Devices**
1. Investigator initiated studies with products should be assigned a consultant reviewer from the Office of Clinical Research Sponsor Support Unit whenever possible.
2. During the discussion of the protocol, the Board members should discuss whether the study meets the criteria for an exemption or NSR determination. The Board Members should discuss each criterion and delineate the rationale as to why the study meets or does not meet that specific criterion.
3. If the Board is unable to determine that the criteria are met, the study team will be required to provide additional rationale or consult with the FDA or other review entity that may make the determination.
4. The minutes should include a description of the criteria and the rationale for why the Board determined the criteria to be met.
5. The exemption or risk determination should be documented in the minutes and in the letter. If the convened IRB defers to FDA, the minutes and letter should also document that determination.
D. Modifications of Protocols to Add/Change a Drug Product and/or Device
   1. If a protocol is modified to add a drug or device, a review should be completed as part of that modification review process.
   2. A determination may need to be reconsidered if the study is modified in a way that impacts any previously made determinations.
OVERVIEW
This section outlines the considerations and determinations the IRB may make when protocols involve Penn Investigators conducting human subjects’ research in foreign countries. When appropriate, IRB staff may consult with local review entities directly to obtain information regarding any submission involving international research.

PROCEDURES
The IRB Administrator should determine if any member of the study team is planning on conducting the research in a foreign country. The online application should detail where the study will be conducted and the personnel who will be traveling. If it is unclear where the study will be conducted and who will be involved at the study site, the IRB Administrator should contact the study team and confirm this information.

To ensure that the protocol is reviewed by individuals with expertise and knowledge of the country, local laws, and cultural context, all studies that are conducted in foreign countries must be approved by the local country’s appropriate regulatory bodies, when applicable. This typically involves approval from an IRB or ethics committee that oversees research at the study site. Additional approvals may be required from government agencies (e.g. Ministries of Health, Education, Labor, etc). The IRB should verify through the study team the regulations governing research in that country and confirm that appropriate approvals have been sought. IRB staff are encouraged to refer to the International Compilation of Human Research Standards document compiled by the Office of Human Research Protections to identify appropriate regulations. The Compilation is stored on the IRB shared drive for staff’s reference.

In the event that the country does not have a local IRB or Ethics Committee that can review the protocol and assess local considerations, the study team must provide the IRB with a review of the research by a local expert which could include a researcher, or representative from a local institution or community organization that has appropriate expertise to review and comment on the appropriateness of the research and the plans for human subjects protections with consideration for any issues related to the local context.

If a non-exempt study is being conducted with non-English speaking subjects, the study team must provide translated copies of the consent form(s). English and translated versions of the consent form(s) should be included in the IRB application.

There are circumstances where Penn IRB approval is needed before consent forms can be translated and local approval can be obtained. In these circumstances, the Penn IRB can review the study to determine if it meets the criteria for approval. However, the Penn IRB will not approve the study. Instead, the IRB will classify the study as administratively finalized. The IRB will issue a letter to the study team indicating that the IRB has determined the criteria for approval have been met but final approval will not be granted until documentation of local approval and/or translated copies of the consent(s) have been provided. The IRB Administrator is responsible for ensuring that the administratively finalized letter includes the appropriate issues that need to be addressed.

When reviewing continuing review and modification applications for research conducted in foreign countries, the IRB staff considers whether any information in the submission warrants input from the local review entity. If consult is needed, IRB staff may request documentation of local IRB or Ethics Committee approval of the action or request confirmation that their approval will be sought before changes are implemented.

Penn investigators are required to submit reports of potential non-compliance, subject complaints, and unanticipated problems to the IRB. This includes reports regarding the actions of Penn study personnel in research conducted in foreign countries and reports for protocols where Penn has a lead site oversight role in research conducted in foreign countries. The IRB will review these reports according to standard operating practices. If consult is needed, IRB staff may request documentation of local IRB or Ethics Committee review of the report and any corrective actions required by local review.
OVERVIEW

This section outlines how the IRB reviews Waivers of HIPAA Authorization and Data Use Agreements. It also describes the specific steps that need to be taken to document the IRB’s review and determination.

PROCEDURES

Waivers of HIPAA Authorization:

Unless there is a noted exception provided by the Director or Associate Director, all requests for HIPAA waivers must include a completed HIPAA waiver request form. If a HIPAA waiver is needed for a study and this form is not provided, the IRB Administrator must request that the form be completed and attached to the submission.

Consideration of a New Request for Waiver of HIPAA authorization:

A new request for a waiver of HIPAA authorization may be attached to an initial or modification submission. When a request is received, the screener should review the request to ensure that the criteria for waiver of HIPAA authorization are met. Any questions related to this determination should be sent to the study team for clarification and/or revision. If any information provided in the HIPAA waiver request form is found to be inaccurate, the administrator should request that the form be revised.

The Screener’s determination and recommendation regarding the acceptability of the waiver request should be documented on either the initial expedited review worksheet or modification worksheet. The worksheet should clearly identify that a HIPAA waiver of authorization is being approved. It should also be clarified whether the process of consent is being waived. The checkbox in PennERA should be selected for HIPAA Waiver of Authorization to ensure the appropriate language will appear in the letter.

If the waiver request includes the disclosure of directly identifiable protected health information (PHI) outside the covered entity which cannot be covered under a data use agreement, the Screener should determine whether convened IRB review of the request is necessary. If convened IRB review is necessary, the submission should be referred to Senior Administrator so submission can be assigned to appropriate Board for review.

Once the waiver request and any other outstanding issues are addressed, the submission may be reviewed at the appropriate level for the submission.

Documentation of the IRB review: IRB Administrative Assistant

Once the submission and HIPAA waiver request are approved, the submission will be returned to an IRB Administrative Assistant for letter generation. During the letter generation process, the Post-Review page in PennERA entry will need to include the list of used/collected and disclosed as determined appropriate with the waiver request. The list of indirect and direct PHI for which use or access has been determined appropriate with the waiver request can be located on the waiver of HIPAA authorization form. This information should be inputted into the comments box found in the post review section in addition to the list of documents included with the review. Once all appropriate fields in PennERA have been updated to reflect the new approval, the IRB Administrative Assistant should generate the approval letter in the communications section by using the “HS – Initial Apprvl – Expd w/HIPAA” or by selecting the HIPAA waiver UDF as part of the exemption letter template. Specific instructions for drafting a letter with a HIPAA waiver are outlined in the separate GDO section for letter drafting workflows.
Consideration of a Modification to Existing HIPAA Waiver:

A change to an existing HIPAA waiver may be attached to a modification or continuing review submission. If a change is included in the continuing review, the administrator should inform the study team that they will need to submit a separate modification request for this review. The continuing review can then be processed, and the approval letter should note that the revised HIPAA waiver was not considered at the time of continuing review. It is not always the case that a revision to the HIPAA waiver attached to a continuing review is readily apparent. The screener is responsible for reviewing any continuing review submission for studies with approved HIPAA waivers to ensure that the study is being conducted in accordance with the initial HIPAA waiver.

Once a modification to the existing HIPAA waiver request has been received, the screener should review the submission to determine if the criteria for waiver of HIPAA authorization are met. Any questions related to this determination should be sent to the study team for clarification and/or revision. The IRB Administrator should review the existing HIPAA waiver request form and determine if revisions are necessary to appropriately incorporate the revised waiver request. If any information provided in the revised HIPAA waiver request form is found to be inaccurate, the IRB Administrator should request that the form be revised.

The IRB Administrator’s determination and recommendation regarding the acceptability of this HIPAA waiver should be documented on the modification worksheet.

If the waiver request includes the disclosure of PHI outside the covered entity that does not qualify for a data use agreement, the Administrator should determine whether convened IRB review of the request is necessary. If convened Privacy Board review is necessary, submission should be referred to Senior Administrator so submission can be assigned to appropriate committee for review.

Once the waiver request and any other outstanding issues are addressed, the submission may be reviewed at the appropriate level for the submission.

Preparatory to Research:

The preparatory research provision permits covered entities to use or disclose protected health information for purposes preparatory to research, such as to aid study recruitment. The preparatory research provision allows such a researcher to identify prospective research participants for purposes of seeking their authorization to use or disclose protected health information for a research study. However, a researcher who is not a part of the covered entity may not use the preparatory research provision to contact prospective research subjects. Rather, the outside researcher could obtain contact information through a waiver of individual authorization by the IRB.

The IRB waiver of authorization may permit the waiver of authorization for the purposes of allowing a researcher to obtain protected health information as necessary to recruit potential research subjects. For example, even if an IRB does not waive informed consent and individual authorization for the study itself, it may waive such authorization to permit the disclosure of protected health information as necessary for the researcher to be able to contact and recruit individuals into the study.

Data Use Agreements:

Data use agreements are required when a limited dataset is being disclosed to an individual or organization outside of one of Penn’s covered entities and authorization from subjects for the disclosure will not be obtained.
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3.7 Waivers of HIPAA Authorization Data Use Agreements
These disclosures may be identified during initial and modification submissions. When these disclosures are identified, the administrator should confirm with the study team that the following criteria are met:
Disclosed dataset qualifies as a limited dataset per HIPAA regulations

The study team will work with the office of Research Services to enter into a data use agreement with the site receiving the dataset or if the data use agreement is attached to the application it may be signed by the Director.

Business Associates Agreements

A business associate agreement is required only where a person or entity is conducting a function or activity regulated by the Administrative Simplification Rules on behalf of a covered entity, such as payment or health care operations, or providing one of the services listed in the definition of “business associate” at 45 CFR 160.103. However, the HIPAA Privacy Rule does not prohibit a covered entity from entering into a business associate contract with a researcher if the covered entity wishes to do so.

In the event that directly identifiable information is disclosed as part of a HIPAA waiver request, the IRB may require that a business associate’s agreement be put in place before the disclosure may take place. The HIPAA waiver request should adequately document why the research is not practicable without the disclosure of directly identifiable PHI.

IRB Procedures for Addressing HIPAA Breaches

A potential breach of confidentiality should be reported to the IRB as a reportable event or deviation. The event should be reviewed by the Associate Director (or the Executive Director’s designee for research related privacy issues) to determine whether the corrective action plan is appropriate, whether convened review is required, or whether the Privacy Office should be notified.

The IRB should defer to the definition of “Breach” as outlined by the HIPAA Breach Notification Rule, 45 CFR §§ 164.400-414, requires HIPAA covered entities and their business associates to provide notification following a breach of unsecured protected health information. If the reportable event constitutes a breach or a potential breach, the Associate Director (with assistance from the IRB staff) should compile a report with the event information including corrective action and plans to contact the affected patients. The local privacy officer or the Privacy Office is responsible for the final breach assessment and should receive this report promptly, as HIPAA breaches are reportable within 60 days of discovery.
OVERVIEW

Conflicts of interest are defined by institutional policies and the federal regulations. This section discusses the procedures that will be implemented when a conflict of interest is identified. This section covers conflicts of interest for IRB Staff, IRB Board Members, Consultants, Investigators, Research Staff, and Organizational/Institutional Conflicts of Interest.

IRB STAFF CONFLICTS OF INTEREST MANAGEMENT

IRB leadership is charged with ensuring that staff members are informed of the University policies and the federal regulations on conflict of interest. The Director and Associate Director will provide education and training to staff on conflict of interest policies. All staff must familiarize themselves with University and federal regulations on conflict of interest.

Staff will self-identify any potential conflicting interests that appear during day to day activities. If staff is conflicted with a protocol, they will remove themselves from consideration of any expedited or convened review of the protocol. The staff will also inform the Director of the conflict for development of a management plan, as applicable.

Any IRB staff conflicts for a study should be documented in PennERA comments to avoid assignment of those study actions to that staff member.

IRB MEMBER AND CONSULTANT CONFLICTS OF INTEREST MANAGEMENT

Members are responsible for identifying conflicts and informing the IRB staff so that staff may take appropriate steps to allow IRB review to continue.

Board Members are informed of the University Policies and the Federal Regulations related to conflicts of interest at the time they join or renew their membership on a Board. Members are given a statement regarding the conflict of interest policies that they must sign to indicate their understanding and agreement to abide by the policies. The IRB Administrator receives this signed form and will file accordingly.

Members with conflicting interests cannot conduct primary or secondary reviews for the studies in which they are engaged in research. While screening full board action items, the IRB Administrator and assistant review the protocol’s personnel list to see if any Board members are engaged in the research. If conflicts are identified during pre-screens the staff logs these conflicts in the agenda tracker and will ensure assignment of the action to an IRB member with no documented conflict. When the agenda is distributed via email, the Board Members asked to inform the IRB staff of any un-identified conflict.

During the meeting the IRB Chair will formally ask the members at the beginning of each meeting whether any member has a conflict. Member responses will be recorded in the minutes. In order for a member to respond appropriately to this question, it is important that he/she have an understanding as to what may constitute a conflict. Current IRB policy states the standard that should guide decisions about conflicting interests is whether an independent observer could reasonably question whether the individual’s actions or decisions about a protocol could be based on factors, other than the rights, welfare and safety of the participants. This means that both actual and perceived conflicts should be reported. Potential sources of conflict that should be reported include, but are not limited to:

- IRB member or his/her immediate family member (spouse or dependent children) has a Significant Financial Interest (SFI) related to the sponsor or other financially interested company that would reasonably appear to be affected by the research. This would include: receipt of payments that exceed $5,000 within the past 12 months;
3.8 Conflicts of Interest and CISC Review

having equity greater than $5,000 in value for public companies and any equity in a private company; or any fiduciary role for the company (e.g., on the Board of Directors or as an officer). In addition, SFIs include a financial interest in intellectual property that is being tested, evaluated, developed in, or its commercial value could be affected by, the protocol being reviewed.

- IRB Member or his/her immediate family member is a member of the research team
- IRB Member’s job status or compensation could be impacted by the review
- The Principal Investigator is the IRB member or his/her immediate family member’s direct supervisor
- Any circumstance that may affect the objectivity of the IRB member
- Any circumstance in which a member is unsure whether a conflict exists

During a convened review of any action, any member with a conflict must leave the room for the discussion and vote. Members with conflicts can only participate in the discussion of that action if they are invited back into the meeting by the Board to answer specific questions.

As Members with conflicting interests must recuse during discussion and voting they do not count towards quorum for that action. Therefore, IRB staff must ensure that a quorum is present for the discussion and during the review of any protocol with an identified conflict. In addition, if a member assigned a primary or secondary review identifies a conflict, the administrator must re-assign that review to an un-conflicted Board member.

Consultants cannot provide reviews for protocols with which they have a conflict. If a consultant review is requested and the consultant identifies a conflict, the IRB Administrator should notify the Director or Associate Director and discuss approaching another consultant. If a consultant is expected to attend a convened IRB meeting, the consultant must leave the room during the discussion and the vote of any protocol with which they are conflicted.

CONFLICTS OF INTEREST FOR INVESTIGATORS AND RESEARCH STAFF

For managing conflicts of interest for investigators and research staff, the Associate Director serves as the COI/CISC Liaison (Backup: Director of Human Research Protections)

- Liaison communicates with Office of the Vice Provost for Research regularly about identified interests
- Liaison communicates COI review information to IRB staff and members
- Liaison communicates with investigators and study coordinators in response to CISC management plans, particularly regarding conflicts of interest disclosures in consent forms.
- Liaison regularly attend meetings of the Conflicts of Interest Standing Committee and report back any issues identified

Conflicts of interest may be identified during any review action. All identified conflicts of interest or involvement of Intellectual Property require direct communication among the screener of the submission, and the CISC Liaison via the following procedures:

**Initial Convened Submission Procedures**

As part of the Completeness Check process, the IRB Administrator is responsible for verifying whether a conflict of interest or involvement of Penn Intellectual Property (IP) has been identified on an initial convened application submission. If a conflict or IP is identified the IRB Administrator must:

1. Document the conflict in the Initial Full Board Checklist
2. Update the Overview section on the summary page of Penn ERA to indicate that CISC review is required
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3.8 Conflicts of Interest and CISC Review

3. Add the following standard stipulation to the Administrative stipulations in Penn ERA for populating to the agenda “IRB approval is contingent upon CISC review of Dr. ‘s financial disclosure. Please note: If a management plan is required, changes to the consent form to include a financial disclosure may be requested by the IRB in response to the CISC review.”

4. Email the COI/CISC Liaison with the protocol title, PI, confirmation code and names of the study team members for whom a conflict has been identified as well as information related to the IP. The COI/CISC Liaison will communicate with the Conflict of Interest Standing Committee. After this point, the Liaison and the IRB Administrator will communicate regularly via email regarding the status and outcome of CISC review and any required action.

5. Post-Meeting:
   a. The Administrator will ensure that the required administrative stipulation is included in the letter to the study team.
   b. Based on the CISC review schedule it is possible for the Administrator to receive an update regarding the conflict review at any time before or after the response is received. The Administrator may communicate with the study team prior to receipt of the response submission if it is known that specific information is required for the response to ensure the response is complete.

6. Upon receipt of the response submission:
   a. The IRB Administrator will contact the COI/CISC Liaison via email for an update on the status of CISC review if one has not already been provided.
   b. Based on the information provided from the COI/CISC Liaison the administrator will check the consent form for appropriate language (if language was necessary) and place for final review by the Board Chair or designee.
   c. If the required changes are not present in the first response the administrator will return the submission to the study team or obtain revisions via email.

Initial Expedited Submission Procedures

As part of the review process for initial expedited submissions, the IRB Administrator is responsible for verifying whether a conflict of interest or involvement of Penn Intellectual Property (IP) has been identified in an initial expedited application submission. If a conflict is identified the Administrator must:

1. Document the conflict in the Initial Expedited Checklist
2. Update the overview section on the summary page of Penn ERA to indicate that CISC review is required
3. Email the COI/CISC Liaison with the protocol title, PI, confirmation code and names of the study team members for whom a conflict has been identified. The COI/CISC Liaison will communicate with the Conflict of Interest Standing Committee. After this point, the Liaison and the IRB Administrator will communicate regularly regarding the status and outcome of CISC review and any required action.
4. If the study is determined to be complete and ready for final review, the Administrator should place the submission up for an “administratively finalized” determination.
   a. The following standard stipulation must be included in the Administrator’s notes to be included in the administratively finalized letter “IRB approval is contingent upon CISC review of Dr. ‘s financial disclosure. Please note: If a management plan is required, changes to the consent form to include a financial disclosure may be requested by the IRB in response to the CISC review.”
   b. The COI/CISC Liaison will notify the Administrator of any required changes to the standardized stipulation based on updates to the CISC review.
5. Assistants are responsible for ensuring that the stipulation is included in the administratively finalized letter.

6. Upon receipt of the response submission: it should be assigned to the Administrator who processed the initial expedited submission.
   a. The IRB Administrator will contact the COI/CISC Liaison via email for an update on the status of CISC review if one has not already been provided.
   b. Based on the information provided from the COI/CISC Liaison the administrator will check the consent form for appropriate language (if language was necessary) and place for final review.
   c. If the required changes are not present in the first response the administrator will return the submission to the study team or obtain revisions via email.

**Convened Continuing Review Submissions (Electronic and Paper)**

Disclosures of financial interests are checked during the continuing review process by the Coordinator processing the action. The section of the continuing review application entitled “Disclosure of Financial Interests” requires the submitter to disclose any financial interests or involvement of Intellectual Property which includes any current or anticipated ownership interest or other financial relationship with any company or entity that sponsors, provides support, or otherwise has a financial interest in the conduct or outcome of this research protocol. If this section is answered “No”, no action or communication with the study team is required. However, if this section is answered “Yes” the procedure below is followed:

1. Document the conflict in the Full Board Continuing Review Checklist.
2. Email the COI/CISC Liaison with the protocol title, PI, confirmation code and names of those for whom a conflict has been identified as well as information related to the IP.
   a. The email should also indicate whether the continuing review response indicates the conflict has been previously reported and whether there are any changes to previously reported conflicts.
   b. The COI/CISC Liaison will communicate with the Conflict of Interest Standing Committee. After this point, the Liaison and the screener will communicate regularly via email regarding the status and outcome of CISC review and any required action.
   c. Email Correspondence regarding conflicts should be attached in the HSER comments (for electronic submissions) or printed and kept with the study file (for paper submissions).
   d. Additionally for paper submissions, the Review Activities in PennERA should be updated to indicate the CISC Liaison has been contacted.

3. The COI/CISC Liaison will provide an update as to whether the study must be conditionally re-approved or if all COI issues are resolved prior to the meeting; the response is also uploaded to the “comments” section. If the study must be conditionally re-approved either due to a new conflict of interest or the requirement that an annual certification be signed this issue will be raised by the Administrator and Assistant at the convened board meeting for acceptance and will be included in the letter to the study team. The Assistant is responsible for ensuring that any requirements related to the COI are included in the letter to the study team.

4. If the study is conditionally re-approved, a Response modification submission will be required to confirm that all CISC requirements have been met. Once the response is received, it will be assigned to the primary assistant for that board for processing.
   a. Upon receipt of the response submission: it should be assigned to the Administrator who processed the initial expedited submission.
   b. The IRB Administrator will contact the COI/CISC Liaison via email for an update on the status of CISC review if one has not already been provided.
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3.8 Conflicts of Interest and CISC Review

c. Based on the information provided from the COI/CISC Liaison the screener will check the consent form for appropriate language (if language was necessary) and place for final review.

d. If any required changes are not present in the first response the screener will return the submission to the study team or obtain revisions via email.

e. If this stipulation was the only stipulation that resulted in conditional approval, the response submission may be assigned directly to the COI/CISC Liaison for review/approval.

Expedited Continuing Review Submissions

Disclosures of financial interests are checked during the continuing review process by the Coordinator processing the action. The section of the continuing review application entitled “Disclosure of Financial Interests” requires the submitter to disclose any financial interests or involvement of Intellectual Property which includes any current or anticipated ownership interest or other financial relationship with any company or entity that sponsors, provides support, or otherwise has a financial interest in the conduct or outcome of this research protocol. If this section is answered “No”, no action or communication is required. However, if this section is answered “Yes” the procedure below is followed:

1. Document the conflict in the Minimal Risk Continuing Review Checklist

2. Email the COI/CISC Liaison with the protocol title, PI, confirmation code and names of those for whom a conflict has been identified as well as information related to the IP.
   a. The email should also indicate whether the continuing review response indicates the conflict has been previously reported and whether there are any changes to previously reported conflicts.
   b. The COI/CISC Liaison will communicate with the Conflict of Interest Standing Committee. After this point, the Liaison and the screener will communicate regularly via email regarding the status and outcome of CISC review and any required action.
   c. Email Correspondence regarding conflicts should be attached in the HSERA comments (for electronic submissions) or printed and kept with the study file (for paper submissions)
   d. Additionally, for paper submissions, the Review Activities in PennERA should be updated to indicate the CISC Liaison has been contacted.

3. The COI/CISC Liaison will provide an update as to whether an annual certification is needed or if CISC review is underway for a newly identified conflict. For studies where either a new management plan or annual certification is required, the administrator will be asked to “hold” the continuing review submission until the expiration date draws near to allow time for resolution of any outstanding conflict issues.

4. When documentation to resolve the conflict is received, the COI/CISC Liaison will notify the screener that the continuing review submission may be placed for final approval. If the date for expiration is imminent and the COI updates have not been received, the administrator should email the COI/CISC Liaison notifying them of the impending expiration. In these cases the continuing review submission should be placed up for conditional re-approval pending resolution of the identified COI issues. The administrator should insert the standard COI stipulation in the reviewer worksheet for inclusion in the letter.
   a. The Assistant is responsible for ensuring that any requirements related to the COI as outlined on the expedited CR worksheet are included in the letter to the study team.
   b. If the study is conditionally re-approved, a response modification submission will be required to confirm all CISC requirements have been met. Once the response is received, it will be assigned for processing.
3.8 Conflicts of Interest and CISC Review

- The screener will contact the COI/CISC Liaison via email for an update on the status of CISC review if one has not already been provided.

- Based on the information provided from the COI/CISC Liaison the screener will check the consent form for appropriate language (if language was necessary) and place for final review.

- If any required changes are not present in the first response the screener will return the submission to the study team or obtain revisions via email.

- If this stipulation was the only stipulation that resulted in conditional approval, the response submission may be assigned directly to the COI/CISC Liaison for review/approval.

Modification Submissions (convened or expedited)

At the time of a modification submission (convened or expedited) a new conflict of interest may be identified.

1. For expedited modifications, the screener should:
   - Document the conflict in the Modification Screening worksheet
   - Send an email to the COI/CISC Liaison with the protocol number, PI name and name of person with a new conflict. The COI/CISC Liaison will communicate with the Conflict of Interest Standing Committee. After this point, the Liaison and the screener will communicate regularly via email regarding the status and outcome of CISC review and any required action.
   - If electronic, the submission should be returned by the Administrator pending provision of a signed management plan or notification of “no conflict” from CISC. The modification may be re-submitted at the time these documents are available.
   - If paper, the modification should be “held” pending confirmation from the CISC Liaison that all conditions are met.
   - Once CISC confirmation has been obtained and communicated to the screener, the submission may be placed for expedited approval if all other issues have been addressed.

2. For convened modifications, the modification submission may be assigned to the convened board for review and scheduled by the Administrator/Assistant.
   - A note should be added to the agenda notes in Penn ERA indicating that a new conflict has been identified and CISC has been notified.
   - The Administrator must send an email to the COI/CISC Liaison reporting the new conflict including the protocol number, PI name and study title as well as the name of the individuals for whom a conflict has been identified. The COI/CISC Liaison will communicate with the Conflict of Interest Standing Committee. After this point, the Liaison and the screener will communicate regularly via email regarding the status and outcome of CISC review and any required action.
   - The COI/CISC Liaison will provide an update as to whether the signed CISC management plan or determination of no conflict has been provided prior to the convened meeting.
     - If available prior to the convened meeting, the update will be provided to the convened board by the Administrator/Assistant. If no action is required based on CISC review, the board will be advised that the conflict issues have been resolved and no issues will be raised. If additional changes are needed based on the update they will be stipulated in the determination letter and a response will be required.
     - If the signed CISC management plan or determination of no conflict is not available prior to the convened board meeting, that information will be provided to the convened board by the
3. Upon receipt of any required response submission: it should be assigned to the Administrator who processed the original submission.
   
   a. The IRB Administrator will contact the COI/CISC Liaison via email for an update on the status of CISC review if one has not already been provided.
   
   b. Based on the information provided from the COI/CISC Liaison the screener will check the consent form for appropriate language (if language was necessary) and place for final review.
   
   c. If any required changes are not present in the first response the screener will return the submission to the study team or obtain revisions via email.
   
   d. If this stipulation was the only stipulation that resulted in withheld approval, the response submission may be assigned directly to the COI/CISC Liaison for review/approval.

ORGANIZATIONAL OR INSTITUTIONAL CONFLICTS OF INTEREST

In addition to individual investigator interests, interests of the institution that could potentially impact the conduct of any specific human subjects’ research protocol or the integrity of the Human Research Protections Program (HRPP) must also be addressed. When institutional interests of this nature are identified, review is required to determine appropriate strategies for mitigating or managing the interests. The review of organizational/institutional conflicts of interest is the responsibility of the Human Research Advisory Committee (HRAC). Procedures for HRAC review of institutional conflict are outlined in detail in a separate ancillary review procedures section of the GDO.
OVERVIEW

The federal regulations place additional requirements on human subjects’ research that involves:
- pregnant women, neonates, or fetuses (Subpart B)
- prisoners (Subpart C)
- children (Subpart D)

This section describes the screening, review and documentation procedures for any review that requires subpart determination (exempt, expedited, and convened board review levels). In addition this section describes the basic requirement for research which may include other populations vulnerable to undue influence or coercion.

SCREENING AND DOCUMENTATION PROCEDURES FOR SUBPART CONSIDERATIONS

For all submissions received, the Screener will determine if a vulnerable population is being recruited and enrolled in the project during the screening process. The HSERA Application Populations page should clearly indicate the vulnerable populations being enrolled. Additionally, the study team should have submitted a completed vulnerable population supplemental form with the application.

If a vulnerable population is being recruited, a subpart review is necessary. The Screener reviews the vulnerable population supplemental form submitted by the researcher. If one was not provided the screener should request that the study team provide one. The Screener should utilize the appropriate vulnerable population screening checklist to determine criteria for approval under the subpart are met. The Screener should communicate with the Director or Designee throughout the screening process to ensure the criteria are met and to determine whether a Prisoner representative should conduct an independent review (for research including subpart C review).

When prisoner representative review is required, the application and any secondary documents to confirm that the inclusion of the prisoners is appropriate, should be provided to the prisoner rep. The representative assists the IRB Administrator by indicating the appropriate subpart category and outlines the questions detailed in the subpart determination form. The IRB Administrator completes the subpart C determination worksheet. The completed worksheet is uploaded to the comments section of HS-ERA for reference by the Director or designee during final approval.

Upon final determination, the IRB correspondence is drafted per usual practice but must include the appropriate Subpart determination language. The screener uses the subpart determination worksheet to determine what language is appropriate and makes notes in the checklist to inform the letter drafter. Template language for every subpart decision is available in the Letter Language Templates document stored on the G Drive. Letters should be drafted using the templates for consistency.

For any NIH/Federally funded project that enrolls prisoner subjects, an OHRP certification letter drafted by the IRB is required. Please see the separate GDO section regarding OHRP certification letters.

MODIFICATIONS: If any protocol is modified to include a vulnerable population, a subpart review should be completed as part of that modification review process. A subpart determination should be also be made if the study is modified in a way that impacts any previously made vulnerable population determinations.

CONTINUING REVIEW: At the time of continuing review, the IRB should confirm whether the study continues to meet the criteria for approval under the subpart via whatever level of review is required for the renewal of the protocol.

EXEMPT REVIEW SUBPART CONSIDERATIONS- Please note the following details regarding vulnerable populations and exempt review:
- Enrollment of pregnant women is not prohibited per any of the exempt categories.
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3.9 Vulnerable Populations Review Processes

- Enrollment of children is permitted for all exempt categories except for category 2. Protocols that enroll children and meet the criteria for exempt category 2 will be reviewed at the expedited level.
- Prisoners cannot participate in any exempt research. If prisoners are identified as participants, an expedited or a convened application is required.

EXPEDITED REVIEW SUBPART CONSIDERATIONS- Please note the following details regarding vulnerable populations and expedited review:

- Enrollment of pregnant women and children are not prohibited per any of the expedited categories, provided the criteria for approval under that subpart have been met.
- Enrollment of prisoners is permitted only under expedited category 5, for research that involves the secondary review of data. A prisoner representative may be consulted during the expedited review process of a Category 5 study. If prisoners are directly interacted with, a convened board review is required. The Screener should consult with the IRB Director or designee to determine if expedited review of prisoner research is appropriate.

CONVENED REVIEW SUBPART CONSIDERATIONS- Please note the following details regarding vulnerable populations and convened review

When preparing a review for the convened board which includes subpart determinations the following are required:

- Complete subpart supplemental forms from the study team
- Appropriate responses to relevant sections of HSERA
- Agenda notes informing the Board members that a subpart determination is required
- Provision of Subpart assessment forms to the Board members prior to and during the convened meeting
- Prisoner Research must be reviewed by IRB 7 or 8
- Confirmation of attendance from a Prisoner Representative when applicable

Please note: If the convened submission includes a complete plan for collection of data from incidental pregnancy, of either the subject or the female partner of a male subject, the subpart review for the collection of data during the pregnancy and any outcome data is reviewed by the Regulatory Representative attending the meeting and the forms are signed and uploaded to document the outcome of the determination for the subpart B and D determinations for data collection during pregnancy and outcome data. If an incomplete plan is provided an administrative stipulation will be raised to address this with the response.

During the discussion of the protocol, the Board members will discuss whether the study meets the criteria for approval under the appropriate subpart. The Board Members use the subpart determination worksheet as a guide. Each criterion for approval under the subpart is discussed and the rationale for why the study meets or does not meet that specific criteria is provided. The IRB Board Members assess the protocol for any controverted issues relating to the inclusion of vulnerable populations and raise the issues for discussion during the meeting along with their resolutions. The Chair will summarize the subpart determination and include it in the final vote motion for the protocol. The Prisoner Representative must be present for the discussion and vote.

The minutes from the meeting will include a description of the subpart criteria and the rationale for why the Board determined the criteria to be met or define the revisions required in order to meet the criteria. The IRB Administrator generating the decision letter includes language detailing the appropriate Subpart determination made during the meeting.

NOTE FOR SUBPART C REVIEWS: If a protocol which previously required convened review is modified and the changes do not affect the prisoner population determination, then a prisoner representative review is not required. At the time of continuing review, if a convened review protocol is in its data analysis stages then a prisoner representative review is not required.
OTHER POPULATIONS VULNERABLE TO UNDUE INFLUENCE OR COERCION
While Federal regulations identify Children, Prisoners, and Pregnant women/neonates/fetuses as vulnerable populations under their respective subparts, the Penn IRB recognizes that other populations included in research may also be vulnerable to influence or coercion.

All study teams must answer a specific question in the HSERA application and at minimum, illustrate how enrolling Penn employees or students will be performed in such a fashion which maintains their autonomy. Study teams will also be expected to consider whether plans are necessary for enrolling and protecting educationally or economically disadvantaged persons. Depending on the nature and design of the research, other vulnerable populations may be identified. As is noted in the HSERA application, this portion of the application is not intended to trigger exclusion of any population that may be vulnerable to influence or coercion for the sake of convenience. The IRB staff should work with the study teams to develop acceptable methods for maintaining the highest feasible level of inclusion in the research.
OVERVIEW
An institution that intends to conduct HHS-supported research involving prisoners as subjects must certify to the
secretary (through OHRP) that the IRB has made the seven findings required under 45 cfr 46.305(a). This section details
the process of preparing an OHRP certification letter for any NIH/federally funded project that enrolls prisoner subjects
under §46.305(a) (1) (C, D). Please note that:

- Subsection(C) is defined as research on conditions particularly affecting prisoners as a class (for example, vaccine
  trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on
  social and psychological problems such as alcoholism, drug addiction, and sexual assaults)

- Subsection(D) defines research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research.

PROCEDURES
The research team should be informed that prisoner enrollment must be on hold until documentation of certification is
received from OHRP. The letter from the IRB to OHRP must include the following:

- Name, address and contact information for the Penn IRB
- Address and contact information for OHRP (available on HHS website)
- Identification of the research protocol
- Relevant grant number and grant coordinator info provided by the study team
- Penn IRB OHRP Assurance #
- IRB # for the Designated IRB
- Dates of IRB meetings in which the protocol was considered including a brief chronology that encompasses date of initial review and date of subpart C review.
- The Director of the IRB should be used in the salutation and a list of the documents included

As any research involving interaction with prisoners requires convened IRB review, the minutes from the IRB Board meeting corresponding to the subpart determination can be used to complete the body of the letter. Each of the 7 criteria for approval for subpart C determination should be incorporated into the letter, each as a separate paragraph. The rationale and the final determination for each of the 7 criteria by the board should be detailed in the body of the letter.

The draft letter should be shared with the IRB director for signature. Any discrepancies or issues with the letter content should be rectified by the letter author prior to director signature.

When compiling the materials needed for forwarding to OHRP the following should be included:
- The OHRP letter signed by the Penn IRB director
- PDF copy of the HSERA application
- Copies of consent forms that will be used with prisoners
- Any subject information documents that will be given to prisoners or other materials relevant to prisoner subjects reviewed by the IRB
- Copy of The HHS Grant
- Copy of the complete subpart supplemental form completed by the study team
OHRP encourages electronic submission of certification requests to be sent to subpartc@hhs.gov. The HHS.gov page for Prisoner Certification Letters to OHRP should be referenced prior to sending to ensure all submission requirements are met.

OHRP will review the certification packet and determine if the project meets the criteria. Once certified, OHRP will send the IRB a certification approval letter. The original letter should be forwarded to the research team so that they may begin enrollment. A copy should be uploaded to HSERA and PennERA or printed and filed in the paper file for IRB record keeping.
OVERVIEW
Certificates of Confidentiality (CoC) are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. Research studies at Penn that seek Certificates of Confidentiality are required to inform the IRB. When this occurs, the IRB application and informed consent form must indicate that the study team has sought or obtained the Certificate of Confidentiality. This section outlines the considerations and determinations the IRB may make when protocols require, seek, and/or obtain a Certificate of Confidentiality. COC’s are available for all NIH funded studies.

PROCEDURES
Before obtaining a COC, NIH may request an assurance agreement signed. The study team will be asked to complete this document. As part of the Director role Tracy will sign – before it gets signed the IRB must verify that the COC is discussed in the ICF.

For ICF language – The IRB staff defers to NIH guidance / template for consent discussion.

The IRB Administrator should determine if the study team is seeking or has obtained a Certificate of Confidentiality when screening the protocol submission. Typically, the data confidentiality section of the online application will indicate that a CoC has been obtained. The Consent form may also discuss a CoC. The IRB Administrator should contact the study team and confirm if they have obtained or are seeking a CoC.

The IRB Administrator reviews the informed consent form to see if it discusses the CoC. The consent form should include a description of the protections and limitations of the CoC, including the circumstances in which the investigators plan to disclose voluntarily identifying information about research participants.

If a study includes sensitive information (such as drug use, illegal conduct, etc.) that may affect a participant’s financial standing, employability or reputation, the Board or the IRB staff may recommend that the study team apply for a certificate.

When obtaining a COC, the study team should ensure that the IRB application and study documents reflect receipt of the COC and how it will be communicated to subjects.

COC is available for all NIH funded studies. The convened board or IRB member reviewer can determined that a COC is required to protect participant data. If the study is not funded by NIH but the IRB or member reviewer determines that a COC is needed, it can be recommended that the study team apply for a COC.
UNIT 3 - IRB REGULATORY OPERATIONS
3.12 Requests for GWAS Certification

OVERVIEW
This section details how the IRB reviews Requests for Certification of Data Submission for Sharing of Data in NIH Supported or Conducted Genome-Wide Association Studies.

PROCEDURES
GWAS Certification requests are most commonly received via email. The Email should include the associated IRB protocol number, the certification email request and a copy of the NIH letter that requires IRB signature with all protocol specific information already filled in.

A basic review of the protocol is conducted to determine if certification of the request is appropriate. IRB Review will include reference to the NIH Genomic Data Sharing guidance document for IRBs to determine if NIH criteria for certification have been met. Any issues identified during the screening process should be brought to the attention of the IRB Directors prior to addressing issues with study teams. Any Director level issues should be presented to the study teams to address prior to signing the letter.

Once it is determined that certification is appropriate, and all criteria are met, the letter is signed by the IRB Director. Signed letters are logged in PennERA as attachments and sent to the study team.
OVERVIEW
Occasionally the IRB receives requests to review research that has already been conducted without IRB approval. These requests may be submitted via email or via the HSERA application system. When this occurs, the IRB does not grant retrospective approval of the research but can consider whether to grant permission to use the data in research publications. The process for considering these requests is described below.

PROCEDURES
If a researcher has contacted the IRB via email or telephone to discuss a project that has been completed without IRB approval, they should be directed to submit a complete application for initial review. During the review of a request for use of data that was collected without IRB approval, the study team should be required to provide the following information:

- A complete HSERA application
- Details about how the study was conducted
- Details about whether consent from subjects was obtained
- The reason why prior IRB approval had not been obtained
- Any required supplemental forms
- Study documents

A standard review of the application and supplemental information should be conducted according to the general IRB SOP.

If the IRB determines that the study would have qualified for exemption, then permission to use the data may be granted.

If the project is minimal risk and was conducted in alignment with research requirements permission to use the data may be provided by an appropriate IRB staff member.

If convened board assessment is required for permission to use the data, the IRB Administrator should add language to the agenda notes to inform the Board that the request is for a study that has been completed and the IRB is asked to consider granting permission to use the data.

After the review of the project, the IRB Administrator should generate a decision letter according to standard practices. This letter should not include any language pertaining to approval. Only language related to “permission to use the data generated” language should be used.
# UNIT 4

## SYSTEMS, DATA ENTRY, COMMUNICATIONS

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OVERVIEW
The Penn IRB uses 2 systems to receive, review and track human research protocols.

- HSERA is the system that researchers use to compile applications and submit to the IRB. Penn IRB staff only have access to read HSERA and to attach comments and correspondence. It is advised that IRB staff review the HSERA submission guidance on the IRB website to become familiar with how study teams submit in this system to understand what information is contained on each page of the application.

- PennERA is a separate data entry system that the Penn IRB staff use to track research approvals. Research teams do not have access to the data that the IRB inserts into PennERA about their protocols. PennERA is also used by other offices in the University but IRB staff only have access to the IRB functions of this program. Data that is entered on each page in PennERA will eventually be compiled into 2 very important documents: IRB Agenda and IRB Minutes. These documents must be as accurate as possible as they serve as the point of access for regulatory bodies (FDA, OHRP, AAHRPP, etc) to review the information collected by the IRB. Therefore, correct data entry is paramount.

This section will provide a brief overview for interacting with these 2 systems. Additional sections of the GDO provide more specific information about HSERA and PennERA.

PENNERA INTRO:
Follow this link to PennERA: https://www.pennera.upenn.edu/ then click LOGON to PennERA. It is advised to bookmark this link since you will be using it every day. A new tab will open. Type in your Pennkey and Password to log in.

To open a protocol, click “Human Subjects” to drop the menu down, then click “Search For”. Type in the protocol # into the “Record Number” field and either press enter on your keyboard or click open/locate.
Click the folder icon under “Actions” to open the protocol. A separate pop-up window will appear which will contain the protocol information. This is the Summary Page. The summary page contains important information regarding the current status of the study as well as other information important to IRB review.

A separate pop-up window will appear which will contain the protocol information. This is the Summary Page. The summary page contains important information regarding the current status of the study as well as other information important to IRB review.

Click on “Submissions” on the left side of the black banner to see the list of all submissions received for this protocol.

On the submissions page will be a list of individual actions that have been received from the study teams. For submissions that originate in HSERA, there will be a submission number that corresponds with a unique code assigned to that item in HSERA. For paper studies, the IRB staff will insert the date of receipt of a paper submission. Each of the columns on this page may be sorted by clicking the name of the column. Most of these fields for a new submission will be blank until the IRB staff completes the data entry during the review.

Click the blue text for any submission under “Type” to open that specific submission.
When the next screen opens, Click Reviews on the left side to open the General review page.

This is the first area where data entry must occur. Each field should be filled in according to the review type and details from HSERA

Once the data is entered on this page to prepare the item for review, the item must now be assigned for final review. Below the Description box on the General Page is the Review section. If a review has not already been created, you must create a review by choosing IRB review as the Method, The appropriate Board and clicking the Add button. This will create a new page to document the review details.

Once the review is created click the blue IRB review to go to the next data entry page
The Next page is the Review details page. Each field on this page must be filled in appropriately as well. Some fields on this page will change as a submission moves through the review process. This page captures:

- When a review took place
- What level of review was applied (Exempt, Expedited, Full, Administrative)
- Who completed a review
- What agenda and minutes document this action will appear on
- The decision for the review
- Information that feeds into the IRB determination letter
- Documentation of minutes for items reviewed by the full board.
- This page is also where letter drafting takes place. Information about letter drafting is discussed elsewhere in the GDO.

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<tr>
<td>Boxed Name</td>
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<td>Expedited Categories</td>
<td>Set</td>
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<tr>
<td>Agenda</td>
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<td>Review/Meeting Date</td>
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**Reviewers**

There are no Reviewers assigned.

**Results**

<table>
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<tr>
<th>Determination</th>
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<td>Determination Date</td>
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<td>Period</td>
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**Update Summary**

<table>
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<th>Determination Comments</th>
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<tbody>
<tr>
<td>Provisions</td>
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</table>

Once data entry is completed, the summary may need to be updated, and a letter may need to be drafted. These processes are discussed elsewhere in the GDO.

Whenever you have completed data entry on any page in PennERA, always click Save in the upper left corner. Whenever you are finished working on an action in pennERA, always click Close to close the window instead of closing the browser window.
The Human Subjects Electronic Research Application (HS-ERA) is available to all researchers at Penn with a valid PennKey and Password.

1. Go to https://medley.isc-seo.upenn.edu/hsProtocol/jsp/fast.do
2. Authenticate with your PennKey and PennKey password.

Most of the IRB staff utilize the 2 functions available under “ORA Administrators”
To locate a protocol and its associated submissions, click on “Find Submissions”
To view a list of specific submissions that are assigned to you to review “click Assign to IRB”

**FIND SUBMISSIONS**
Type in the Protocol number then click the “Filter” button Do NOT press Enter on your Keyboard
Click the blue column headings (submission date, type, etc) to sort the submissions if needed. To open a submission, click “Review” on the far-right side. Clicking the Eyeglasses will provide an abbreviated view
EYEGASSES
To see the review history of a submission, click the eyeglasses button. The eyeglasses view is strictly an overview of the assessments and actions by the IRB staff as it relates to the submission (comments regarding the review, the review decision, and decision letter). Depending on whether the IRB had to return a submission to the study team, the Revision history section may include a set of hyperlinks which create a link between the eyeglasses page of each draft of a submission that has been received. This example was not returned so no hyperlinks are shown.
You may also use the buttons along the top to view the application as a running PDF, or a printer friendly version. Clicking View Protocol Application Form will open the application in a similar manner that the study team sees when they fill it out, so you may review the full contents.
REVIEW PAGE
The Review page provides access to the complete information for the review in different ways. You may either review the entire application or review each section individually. When changes are made to an application you will be provided with a Show Tracked button next to the Show Clean button for each section. When viewing tracked changes, text removal will be red lined and text addition will be green lined, so you may easily assess the changes. The expanding documents section will group documents that are attached with each draft. Clicking any of the blue underlined text will expand that section.

### Protocol Application Form
You may view the entire protocol application form:
- **Clean protocol application** (shows printer-friendly version)
- **Protocol application w/ tracked changes** (shows printer-friendly tracked version)

### OR
You may view the protocol application form by section:

#### IRB Facesheet
- **Basic Info**
  - show clean
  - show tracked
- **Personnel**
  - show clean
  - show tracked
- **Bio**
  - show clean
  - show tracked
- **Sponsors**
  - show clean
- **Sites**
  - show clean

#### Protocol Summary
- **Protocol**
  - show clean
  - show tracked
- **Populations**
  - show clean
  - show tracked
- **Procedures**
  - show clean
  - show tracked
- **Consent**
  - show clean
  - show tracked
- **Risk/Benefit**
  - show clean
  - show tracked

#### Documents
- show documents uploaded with (bdggheec) created on 09/27/2013
- show documents uploaded with (bdfebedf) created on 09/12/2013
- show documents uploaded with (bdfhhig) created on 07/23/2013
- show all documents

#### Comments
- show comments

#### IRB Correspondence
- show IRB correspondence

#### Ancillary Committee Correspondence
- show Ancillary Committee correspondence

#### IRB Review History
- show IRB review history
ASSIGN TO IRB
Also referred to as your “Queue” the Assign to IRB section in HSERA will show you individual submissions that are assigned to you for processing. For most submissions, once the assignment is complete and a letter has been issued, the assignment will drop off your queue. Some submissions with certain determinations will stick around forever. Learning to use, sort, and manage the queue is critical for all IRB staff. Most staff members manage their assignments by using the HSERA Queue in conjunction with Outlook since each assignment will be communicated to you in an individual email message.

Your Queue may be sorted by clicking any column header (for example if you want to view your assignments in the order that the studies expire or in the order that they were received). You can also use the filters to narrow your view of the Queue (this is especially useful once you have many old submissions that are complete but will not drop off your queue.)

The eyeglasses and review buttons operate the same when viewing the queue. The Assign button is for either returning the submission to the study team OR creating the link between HSERA and PennERA and to create the action in PennERA since this does not happen automatically. Please see the separate GDO sections about Assigning and Returning submissions in HSERA.
**OVERVIEW**

As noted in both the Expedited and Convened assignment workflow GDO sections; if concerns are raised during the review process of any HSERA submission, revisions and responses from the study team should either be received via email or the submission should be returned. There are 2 essential time points when a submission could be returned – during screening before final review or after final review.

This section serves to provide instruction for appropriately returning HSERA submissions. Please note that submissions received for paper studies cannot be returned.

**IDENTIFYING WHEN A SUBMISSION SHOULD BE RETURNED**

**During Screening**

Submissions returned to the study team during screening are returned for revisions. Deciding whether to return a submission as opposed to obtaining clarification via email is often a choice of preference for the screener who is assigned to the action under review. Appropriate rationale for returning could include but is not limited to:

- **Incompleteness** – the HSERA application doesn’t include the appropriate information or the correct documents were not attached
- **Inconsistencies** – information in sections of the HSERA application don’t align with information within documents attached to the application
- **Request from study team** – sometimes a study team will submit and then realize they forgot something and ask for the submission to be returned
- **Wrong submission type** – For example a study team submits the exempt version of the initial application but their research does not qualify for exempt review. The submission must be returned so they may answer additional screening questions. OR if a study team is submitting for renewal they cannot do so by submitting a modification via HSERA, they must submit a Continuing Review. If a wrong submission is received, the study team should be directly instructed to delete the incorrect submission from “items to be resubmitted” to avoid causing issues in the future with open ended items.
- **Note regarding Paper submissions** – paper submissions cannot be returned. Any issues raised during screening of a paper submission should be addressed with the study team via email only.

**After Final Review**

Submissions returned to the study team after a determination has been made are returned for responses. As a result of the convened review process, the IRB may raise stipulations that require response from the study team. In order to respond to convened stipulations the following must occur:

- **Withheld or Tabled Initial review** – the application should be returned to the study team once the IRB Determination letter is finalized which identifies and communicates the required areas of response.
- **Withheld or Tabled Modification** - the application should be returned to the study team once the IRB Determination letter is finalized which identifies and communicates the required areas of response.
- **Conditional RE-approval Continuing Review** - IRB Determination letter is finalized which identifies and communicates the required areas of response. The study team is then required to create a new modification to respond to the board’s concerns. The Continuing Review submission is NOT returned.
- **Responses required after Convened review of Deviations** - IRB Determination letter is finalized which identifies and communicates the required areas of response. The study team is then required to create a new submission to respond to the board’s concerns. The Deviation submission is NOT returned. It must be “Accepted pending responses”
4.1 Returning HSERA Submissions

**Reportable Events** - IRB Determination letter is finalized which identifies and communicates the required areas of response. The study team is then required to create a new submission to respond to the board’s concerns. The Reportable Event submission is **NOT** returned. It must be “Accepted pending responses”

**Exceptions** - The application may be returned to the study team once the IRB Determination letter is finalized which identifies and communicates the required areas of response.

**Note regarding Paper submissions** – Paper submissions cannot be returned. Any stipulations raised for paper Modifications, Continuing Reviews, Reportable Events, Deviations or Exceptions will require the study team to submit a formal response via Modification. They should check the box on the modification form to indicate they are responding to issues raised.

**HOW TO RETURN AN HSERA SUBMISSION**

The final steps taken to return a submission in HSERA are directly related to when and why a submission is being returned.

1. Locate the submission in the Assign to IRB section of HSERA
2. Click Assign
3. On the next screen, click Add a comment

**Protocol description:** The main purpose of this study is to find the best dose of hydroxychloroquine with regorafenib and entinostat.

**Resubmission:** Yes

**Application type:** FULL

**You have the option to:**

- Add correspondence
4. On the next screen, insert a message to the study team into the box provided informing them that their submission is being returned and why. If you already contacted the study team via email with full details about the required revisions, you can either paste them again here or just instruct them to reference that email for the full details. Once your comment is complete, click “add comment as IRB administrator”. Please be aware that the message you place into this box will be sent to the study team via email by the system so should be composed as you would a professional email using outlook.

5. Once you add your comment you are brought back on the previous screen and must choose one of the 4 Red options under “Return to Submitter”. The choice made here will depend entirely upon why the submission is being returned.

Once you click one of these red buttons, the submission will be returned to the study team. The submission is assigned a new confirmation code and is available in HSERA under “items to be resubmitted”. Simultaneously, an automated email is generated by the system to the study team with basic information about the submission that is being returned (confirmation code, protocol number, title, PI) as well as the complete text you inserted into your comment in step 4. Once a submission is returned, the IRB cannot perform any additional actions on that submission until after the study team resubmits. A single submission may be returned multiple times if necessary. Multiple returns is not uncommon for Initial Expedited Review process.

**CHOOSING THE RIGHT MECHANISM FOR RETURN:**

- **Return to investigator for revision** – this option is for returning submissions during the screening process where revisions to the application or attachments is needed before you can place it for approval or assign it to a convened agenda. Submissions returned this way will require that the PI approve the submission again before the IRB receives it. This option should NOT be used to return a submission that received convened review and must respond to stipulations.

- **Return to investigator for revision without approval** - this option is also for returning submissions during the screening process where revisions to the application or attachments is needed before you can place it for approval or assign it to a convened agenda. Submissions returned this way will NOT require that the PI approve the submission again before the IRB receives it. Any study contact who has access to make revisions may produce the required revisions and re-submit. This option should NOT be used to return a submission that received convened review and must respond to stipulations.

- **Return to investigator for response** - this option is for returning submissions where the board raised stipulations that require a response. Submissions returned this way will require that the PI approve the submission again before the IRB receives it. This option should NOT be used to return a submission during the screening process.

- **Return to investigator for response without approval** - this option is for returning submissions where the board raised stipulations that require a response. Submissions returned this way will not require that the PI approve the submission again before the IRB receives it. Any study contact who has access to make revisions may produce the required response and re-submit. This option should NOT be used to return a submission during the screening process.

Choosing whether to require PI approval of revisions or responses in HSERA is at the discretion of the screener or the Board depending on the situation and the nature of the revisions / response.
OVERVIEW
All submission received in HSERA must be fed over to the PennERA system to:
- Create a protocol number for new studies
- Document the review
- Receive final review by IRB directors
- Assign actions to an agenda
- Assign actions for IRB Member review
This section outlines the process for assigning from HSERA to PennERA.

PROCEDURES
All HSERA actions must be assigned from the Assign to IRB section of HSERA (also referred to as your Queue). You can only assign actions that are assigned to you – you cannot assign an action that either has not been assigned to anyone yet or has been assigned to someone else.

IN HSERA:
1. Open the Assign to IRB section of HSERA
2. Locate the submission you would like to assign (you can sort by protocol # or confirmation code or just scroll through the list
3. Click Assign on the far right
4. On the new screen that appears, click the radial button next to the board you want to assign to and click Submit. On the next screen click Confirm.
5. After clicking confirm, HSERA will trigger a linking process with PennERA and an action will be created on the Submissions page in PennERA for this study. IF the submission is a new study, this process will create a new protocol in PennERA and generate the protocol number that the IRB will use going forward to reference this study.
UNIT 4 – SYSTEMS, DATA ENTRY, COMMUNICATIONS
4.2 Assigning A Reviewer

In PennERA:
1. Type the protocol number into the “Record Number” field in pennERA
2. Open the protocol by clicking the folder icon under Actions
3. From the Summary Page, Click “Submissions” in the top left on the black ribbon menu
4. Look for the submission which has a determination of “Logged” (if multiple submissions have been received and are pending review simultaneously, be careful to choose the correct one based on type and investigator submission date)
5. Once you have found the submission click the blue text on the far left in the Type Column to open the action.
6. Complete any necessary data entry on the General page (for HSERA you must insert the confirmation code for this action into the topmost field so that the action may be easily identified going forward)
7. Once data entry is complete, go to the Review ribbon and click the blue text next to the radial button that says “IRB Review” to open the Review details page
8. Make sure the review category is correct
9. Make sure the Board name is correct
10. Set the determination to “Pending” (this is important)
11. On the Reviewer Ribbon, click Add/Change
12. In the popup window choose the appropriate reviewer from the list of personnel on the left side under “Board Members” (do not choose anyone from Assoc. Personnel). Click the name to highlight it and click Select. When the name shows in the Active Reviewer ribbon, click save then click close. The screen will refresh and the reviewer you chose should now be displayed on the Review details page and the assignment is complete.
13. Click save in PennERA in the upper Left corner before clicking Done. (always click Done in pennERA to close the window instead of closing the browser window)
14. Once the submission is set to Pending, HSERA will change from Logged to Pending in the PenERA Protocol Status column

GUIDANCE
- When viewing your HSERA Queue to assign submissions, you will want to be sure the PennERA Protocol Status column is blank for the submission you want to feed over. If there is text in that column, that means the PennERA action has already been created and you do not need to feed the submission, you just need to go to PennERA and locate the action
- Once a submission has been successfully fed over, the PennERA protocol status in HSERA will appear as “Logged”. This means you can now open the related action in PennERA and any determinations made in PennERA will be linked to the submission in HSERA.
- If the submission you are feeding over is the first initial submission, once the study is in logged status, HSERA will also assign and display the Protocol number that you will need to find the study in PennERA. This protocol number will be used and referenced for the duration of the study in all IRB correspondences.
- Due to the functionality of the questions on the BIO/HRPP page, Initial submissions should be fed over to PennERA as soon as possible so that the ancillary review offices receive the email pings generated by the responses to those questions.
4.2 Assigning A Reviewer

- Other types of submissions should be fed over to PennERA when they are ready for final review. It is best to avoid immediately assigning modifications and continuing reviews since they may need to be returned to the study team.

- Actions that are fed over to PennERA which are then returned must be marked as Issue Identified and CANNOT be used to document the review of the submission when it comes back in.

- Choosing the appropriate board is important to consider. Here is some general guidance:
  - New Expedited / Exempt studies always get assigned to IRB 7 or 8
    - IRB 7 is Biomedical studies
    - IRB 8 is Social Behavioral studies
  - New full board or convened studies are assigned to a board based on available expertise on that board. Typically, assignments for a new study that requires convened review are only assigned to the administrator for the board that will be conducting the review, the details of your assignment will indicate which board will be reviewing the study if the admin covers more than one board.
  - Continuing reviews should be assigned to whatever board is listed in pennERA (established at initial review) OR in the case of Convened Review – whichever board will be conducting the convened review (in some cases expiration date, submission timing, agenda volume will prevent review by the assigned board).
  - Expedited Modifications, Exceptions, Deviations, and Reportable Events should be assigned to whatever board is listed in PennERA Unless Chair review is required. If Chair review is required, you must choose the board associated with the chair that will be conducting the review.
  - Convened Modifications, Exceptions, Deviations, and Reportable Events should be assigned to whichever board will be conducting the review (this may not align with the board identified at initial review documented on the PennERA Summary page).

- If you choose the wrong board when assigning from HSERA, you may revise the assignment once the action appears in PennERA.

- When assigning expedited reviews in PennERA be sure to choose the appropriate Director reviewer according to the logic outlined in the Expedited Assignment Workflow section of the GDO.

- When assigning reviewers for convened actions on a full board agenda, be sure to review the board roster to choose a person on your board who has appropriate expertise for the protocol design and intervention as well as appropriate experience as an IRB member based on the complexity of the submission. You should consult with your Reg Rep about board assignments until you get comfortable with your board members strengths.
OVERVIEW

The Summary page of PennERA gives the IRB staff the ability to see the overall status and important regulatory information about a study at quick glance. It is crucial that the Summary be updated and maintained appropriately throughout the life of the study. This section provides detailed information about the Summary page fields and how they should be filled in. Additional information about updating the summary is provided in other GDO sections.

SUMMARY PAGE FIELDS

<table>
<thead>
<tr>
<th>Field</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Record Number</strong></td>
<td>Not editable. Generates when initial submission from HSERA is fed over to PennERA.</td>
</tr>
<tr>
<td><strong>Created on</strong></td>
<td>Not editable. Is the date the study record was created in Penn ERA.</td>
</tr>
<tr>
<td><strong>Initial Submission Date</strong></td>
<td>Is the date the study record was created in Penn ERA.</td>
</tr>
<tr>
<td><strong>Research Type</strong></td>
<td>Required for Full &amp; Expedited. Not required for reliance, administrative or Exempt.</td>
</tr>
<tr>
<td><strong>Risk Level</strong></td>
<td>Required for Full and Expedited Review categories, not required for administrative, reliance or exempt categories</td>
</tr>
<tr>
<td><strong>Reviewers</strong></td>
<td>Ignore this</td>
</tr>
<tr>
<td><strong>Determination Date</strong></td>
<td>Required for everything. Should never be blank after Initial approval. Should only be updated with Continuing Review.</td>
</tr>
<tr>
<td><strong>Approved To</strong></td>
<td>Also known as the Expiration date of the study. Required for studies that need continuing review. Should only be updated with Initial and Continuing Review</td>
</tr>
<tr>
<td><strong>Short Title</strong></td>
<td>Make sure this matches the short title provided in HSERA. Does NOT automatically update when HSERA is revised.</td>
</tr>
<tr>
<td><strong>Full Title</strong></td>
<td>Make sure this matches the full title provided in HSERA. Does NOT automatically update when HSERA is revised.</td>
</tr>
<tr>
<td><strong>Objectives and Purposes</strong></td>
<td>HSERA information pulls to here. Paper studies must have manual data entry</td>
</tr>
<tr>
<td><strong>Overview</strong></td>
<td>This box is crucial for noting additional considerations. If a study includes Subparts, ancillary review, Drug or Device determinations</td>
</tr>
</tbody>
</table>

**Change and Management buttons - IGNORE**

<table>
<thead>
<tr>
<th>Field</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Submitted on</strong></td>
<td>Required. Date study was received by IRB in HSERA – is editable for paper study purposes. Should not be updated after study receipt.</td>
</tr>
<tr>
<td><strong>Review Category</strong></td>
<td>Required. Pertains to what sort of regulations we are applying.</td>
</tr>
<tr>
<td><strong>Original Meeting Date</strong></td>
<td>Should be the date that the initial review occurred. Make sure you don’t update it with the summary after initial review is complete.</td>
</tr>
<tr>
<td><strong>Board Name</strong></td>
<td>Required. Should only be changed after Initial review after consulting with board administrator or reg rep.</td>
</tr>
<tr>
<td><strong>Determination</strong></td>
<td>Required</td>
</tr>
<tr>
<td><strong>Approved From</strong></td>
<td>Required for studies that need continuing review. Should only be updated with Initial and Continuing Review</td>
</tr>
</tbody>
</table>
SUMMARY PAGE DETERMINATIONS EXPLAINED

<table>
<thead>
<tr>
<th>DETERMINATION ON SUMMARY PAGE</th>
<th>EXPLANATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>PENDING (TEMPORARY)</td>
<td>The initial submission was received and screened but is pending final review by either the board or director. This determination will change once the final review is complete and the summary should be updated to reflect that review outcome. The determination may be any of the following determinations in this guidance table.</td>
</tr>
<tr>
<td>APPROVED</td>
<td>The initial or most recent cr has been completed with no significant issues found that should prevent the study from progressing as planned. Should not be used for reliance or CHOP cooperative agreement scenarios</td>
</tr>
<tr>
<td>APPROVED CONCEPT IN PRINCIPLE</td>
<td>A prime/umbrella grant or “Just in Time” has been approved or renewed. Research cannot be done, this is for funding only and is thus an administrative review category. This determination will not change until the Prime protocol is closed or if a major modification to begin the study related to the “just in time” study is approved.</td>
</tr>
</tbody>
</table>

Other Information

- Pending Issue that May Impact Future Reviews check box & Description: This should be used to describe any issues that are not formal stipulations in a letter. Whatever needs to be completed should be mentioned in this box along with the date, name of the person who put the note there and a description of when the note can be removed (if appropriate). Be detailed and directive.
- Penn IND Holder: check box if Penn investigator, OCR or University holds IND
- IND Holder: Name the IND holder
- IND/IDE Number: Insert IND/IDE number
- Investigator Initiated Clinical Trial: check box if yes
- NIH GDS Certification Granted: check box if yes
- NIH GDS Certification Date: insert Cert. date
- PENN IRB of Record: Check box if Penn serves as IRB for CHOP
- CHOP IRB of Record: Check box if CHOP serves as IRB of record for Penn
- Date of Authorization: Insert date of finalized Penn/CHOP agreement
- IRB Authorization Agreement – Check if Penn is IRB of Record for any non-CHOP sites
- IRB Authorization Agreement – Check if a non-CHOP IRB serves as IRB of record for Penn
- Name of Institution(s)/Comments: If Penn is relying, name the IRB that Penn Relies on (e.g. Western IRB) OR keep a list of all sites for which Penn Serves as the IRB for record (e.g. University of Michigan)
- Change Required PI Contacted: check if contract was reviewed and the PI was informed the injury language needs revisions
- Consent Change Complete: check when required revisions were received and accepted
- Contract Review Completed: Check when contract review is complete
- Comments: make a note of the date when the contract review took place, revisions were requested, or language was accepted.
Continuing review of a prime grant should always result in this determination even though the hsera determination is just approved.

**ACKNOWLEDGED**
For reliance agreements it indicates that we have agreed to rely but the paperwork is incomplete. In the case of a reliance agreement, this status would be changed to Approved Relying IRB once all the paperwork is received. Any administrative action that does not have another appropriate determination and does not require any future renewal or follow up would remain administrative acknowledged forever.

**WITHHELD APPROVAL (TEMPORARY)**
The initial full board review of the study noted issues that require responses from the study team that can be reviewed expedited. This status would be changed to “approved” once the response submission is approved and all stipulations have been met.

**CONDITIONAL RE-APPROVAL (TEMPORARY)**
The most recent continuing review noted issues that require responses. This status would be changed to “approved” once the response submission is approved and all stipulations have been met.

**ISSUE IDENTIFIED**
This could potentially be seen on the summary page if an expedited Initial is returned for revisions and the analyst sets the summary to “Issue Identified” in addition to the submission. This should not appear on the summary page when a letter is being drafted.

**COMPLETED**
A closure submission has been approved. HSERA will say “Approved” but Penn ERA should say “Completed” on both the submission and the summary page.

**ACCEPTED**
This should never appear on the Summary page.

**EXPIRED**
The study expired. This is not automatic- someone must manually set the determination to this. When running reports it is important to include the “Approved To” date in the report for each result so that studies that have been long expired will not be considered with those that are current since they will still say “Approved” in the determination field.

**TABLED (TEMPORARY)**
The initial full board review of the study noted issues that require responses from the study team and those responses will also require full board review. This status would be changed to either Withheld Approval OR Approved after the response has been reviewed depending on the outcome.

**ACKNOWLEDGED (CHOP-PENN)**
CHOP is the IRB of record.

**APPROVED (CHOP-PENN)**
We are the IRB of record for CHOP.

**APPROVED (NO CR)**
Study meets 2018 common rule criteria for minimal risk study but not exempt study. Modifications will still be required. Continuing Review is NOT required.

**APPROVED RELYING IRB**
We have agreed to rely on another IRB (Not CHOP)

**APPROVED RELYING ON CCH IRB**
We have agreed to rely specifically on the Chester County Hospital IRB

**APPROVED CONTRACT PENDING (TEMPORARY)**
The study meets all IRB criteria for approval but we cannot release consent forms yet because the injury language in the ICF must be determined by the contract office at ORS. When the contract is approved and we screen the ICF and approve the language this will be changed to Approved.

**APPROVED AS DUPLICATE FOR RBN**
The billing department asked for a duplicate record of an existing study for research billing number.

**APPROVED SPONSOR ROLE ONLY**
The Penn IRB is helping out a researcher by having Tracy serve as the PI. These are rare.
TEMPORARY DETERMINATIONS

Some determinations listed above in purple are noted as Temporary. This is because they are subject to change based on information requested from the study team or the basic IRB review process.

If you are assigned anything for a study with one of these temporary determinations on the summary page, you are responsible for assessing whether the thing you are screening should result in updates to any of the information on the summary page of Penn era or special actions while drafting the determination letter. Important things to think about include:

- Are there appropriate determination and expiration dates noted?
- Does a consent form need to be stamped and released?
- Has the study team been told everything they need to know about the IRB review of the study?

(Note: the admin finalized letter does not include expiration date or expedited categories or risk level notation like a normal initial approval letter would.)

If any information should be updated as a result of your assignment, this should be identified for the final reviewer as part of your screening (because they are trying to assess the overall impact of the action they are reviewing) and to also explain everything to the letter drafter.

CHOOSING THE RIGHT DETERMINATION

Some Determinations are only appropriate for certain review categories or risk levels. Not every study gets an expiration date. It’s important to know these things so that the automated actions that Penn ERA performs in the background function correctly (like sending reminder emails for expirations). The table below provides an overview of the appropriate combinations of data that should be reflected on the Summary page.

<table>
<thead>
<tr>
<th>DETERMINATION ON SUMMARY PAGE</th>
<th>APPROPRIATE REVIEW CATEGORIES</th>
<th>APPROPRIATE RISK LEVELS</th>
<th>EXPIRATION DATE NEEDED?</th>
</tr>
</thead>
<tbody>
<tr>
<td>PENDING (TEMPORARY)</td>
<td>ANY</td>
<td>ANY</td>
<td>NO</td>
</tr>
<tr>
<td>APPROVED</td>
<td>ANY</td>
<td>ANY</td>
<td>Yes</td>
</tr>
</tbody>
</table>
## 4.3 PennERA Summary Page Data Entry Guidelines

The purpose of the table above is to better inform the IRB staff to recognize data entry errors. For example:

If the summary page shows a determination of Exempted with a review category of Expedited but does not include an expiration date, something has gone wrong and needs to be corrected since this combination of information should not exist.

Similarly, if a the summary page shows a determination of Acknowledged with a review category of Full, something has gone wrong and needs to be corrected.

Most mistakes found on the summary page are a result of improper procedures being followed when doing an “update summary” during the letter drafting process. Please see the separate GDO section about updating the summary.

<table>
<thead>
<tr>
<th>Decision Category</th>
<th>Administrative</th>
<th>Reliance</th>
<th>MINIM</th>
<th>GTMR</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved Concept in Principle</td>
<td>Administrative</td>
<td>NONE</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Acknowledged</td>
<td>Administrative, Reliance</td>
<td>NONE</td>
<td></td>
<td></td>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>Withheld Approval (Temporary)</td>
<td>FULL</td>
<td>GREATER THAN</td>
<td>MINIMAL</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Conditional Re-Approval (Temporary)</td>
<td>FULL, Expedited</td>
<td>MINIMAL, GTMR</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Issue Identified</td>
<td>Not Typical for Summary Page</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>Completed</td>
<td>ANY</td>
<td>ANY</td>
<td></td>
<td></td>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>Accepted</td>
<td>Never on the Summary Page</td>
<td>Never on Summary</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expired</td>
<td>ANY</td>
<td>ANY</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Tabled (Temporary)</td>
<td>FULL</td>
<td>GTMR</td>
<td></td>
<td></td>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>Acknowledged (Chop-Penn)</td>
<td>Reliance</td>
<td>ANY</td>
<td></td>
<td></td>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>Approved (Chop-Penn)</td>
<td>Expedited, Full</td>
<td>ANY</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Approved (No CR)</td>
<td>Expedited Under New Rule</td>
<td>ANY</td>
<td></td>
<td></td>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>Approved Relying IRB</td>
<td>Reliance</td>
<td>NONE</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Approved Relying on CCH IRB</td>
<td>Administrative</td>
<td>NONE</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Approved Contract Pending (Temporary)</td>
<td>FULL, Expedited</td>
<td>ANY</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Approved as Duplicate for RBN</td>
<td>Administrative</td>
<td>NONE</td>
<td></td>
<td></td>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>Approved Sponsor Role Only</td>
<td>Administrative</td>
<td>NONE</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Exempted</td>
<td>Exempt</td>
<td>NONE</td>
<td></td>
<td></td>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>Not Human Subjects Research</td>
<td>Administrative (QI, NHSR)</td>
<td>NONE</td>
<td></td>
<td></td>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>Disapproved</td>
<td>ANY</td>
<td>ANY</td>
<td></td>
<td></td>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>Withdrawn Submission</td>
<td>ANY</td>
<td>ANY</td>
<td></td>
<td></td>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>Logged (Temporary)</td>
<td>ANY</td>
<td>ANY</td>
<td></td>
<td></td>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>Administratively Finalized (Temporary)</td>
<td>FULL, Expedited</td>
<td>ANY</td>
<td></td>
<td></td>
<td></td>
<td>NO</td>
</tr>
<tr>
<td>No Continuing Review Required (No Longer in Use)</td>
<td>Was previously used for Exempt studies</td>
<td>NONE</td>
<td></td>
<td></td>
<td></td>
<td>NO</td>
</tr>
</tbody>
</table>
OVERVIEW
The summary page of PennERA contains information about the status, expiration date and other regulatory information regarding the study Overall (not data related to any one specific review). As a result of some reviews, changes to the summary page may be necessary. This section provides a general overview of how updating the summary will occur and how to appropriately make updates.

WHEN TO UPDATE THE SUMMARY
Updates to the summary must be performed after a decision for a submission has been made during the letter drafting process. Updating the summary during letter drafting is crucial as the IRB letter templates pull the updated information from the summary page into the letter. The letter drafter should ensure all data entry for the action is correct, then update the summary, then draft the letter.

HOW TO UPDATE THE SUMMARY
In PennERA there are Update Summary buttons provided in multiple areas for convenience. Regardless of where the button appears, clicking it will trigger the same task to be performed which requires critical thinking on the part of the person performing the update.

The update summary function works by comparing the data entry completed on the page you are on in a submission (i.e. the “Current Record” column) with the information presently reflected on the summary page (i.e. the “Summary Record” column). It is providing you the option to change the information on the summary page to reflect the new information in the Current Record.

If there are values that are different between the Summary Record and the Current Record, the update summary screen will show you what information is in each field on both the summary and the current record and provide a check box for you to choose whether or not the information on the summary gets updated with the information in the matching field in the page you are on.

If the values are the SAME the update Summary page line for that item will be blank and a checkbox will not be provided because there is nothing to update.

The letter drafter should use their knowledge of the IRB data entry and review process as well as notes provided from the screener of the submission to appropriately update the summary for every letter assignment. Some general notes on updating the summary:

- **INITIAL REVIEW:** When drafting an initial expedited letter **ALL OF THE BOXES** on the summary update screen should be selected for update because the summary has not been set yet since it is the first review.
  - After Initial review, you must pay close attention to what needs to be updated on the summary depending on the type of submission you are working on and the outcome of that review.
- **MODIFICATIONS:** - when drafting letters for modifications, unless the modification includes changes to other basic information on the summary page, you are expected to push the update summary button before drafting modifications letters to make sure the most recent personnel are listed on the letter. The “All Inv. (excluding PI)” box is the only box to be checked (unless the review notes indicate other revisions are necessary). Always check with the submission screener before updating any other sections with a modification review.
- **CONTINUING REVIEW:** when drafting letters for continuing review, you are expected to push the update summary button before drafting your letter to make sure the most recent personnel are listed on the letter AND to push the new study approval status and expiration dates to the summary page. This includes checking boxes appropriately for the **Determination, Determination Date, Approved From & Approved To** sections of the update summary page.
4.4 Updating PennERA Summary

- **DEVATIONS, EXCEPTIONS, REPORTABLE EVENTS** – **NEVER UPDATE THE SUMMARY WHEN DRAFTING LETTERS FOR THESE ACTION TYPES.**

- After initial review of the study, the following items should **NEVER** be updated on the summary page:
  - Review/Meeting Date (this date must remain the same to track the age of the study)
  - Submitted on Date (this date must remain the same to track the age of the study)

- After initial review of the study the following items should **RARELY** be updated on the summary page:
  - Review Board
  - Review Category
  - PI
  - Primary Assoc. Dept.
  - Risk Level
  - **ALWAYS CHECK WITH AN ADMIN BEFORE UPDATING THESE**

- After initial review the following items will be updated regularly over the life of the study, however care must be taken to update correctly and at the appropriate times:
  - All Inv. (excluding PI)
  - Determination
  - Determination Date
  - Date From
  - Date To

Example for screen shot above:
If one were to check the boxes available and click the update summary button in the top right, the summary page for this study would no longer have an approval date (Date From,) it would no longer have an expiration date (Date to), and it would no longer have a submitted-on date. The information that is currently on the summary page for those fields would be updated to show blank spaces as indicated in the column for “Current Record”. This is a major update and likely not correct. Removing the approval dates (or any other information) from the summary should only occur with direct instruction.
OVERVIEW

Management of a convened board requires IRB administrators to build an agenda once a month that contains all the action items planned for review at that month’s meeting. The agenda is sent to the board members to inform them of their assignments, so they may prepare for the meeting.

PROCEDURES

Building an Agenda:

1. Log in to PennERA
2. Go to Program Tools
3. Find your IRB and click Meetings
4. Find your meeting date and click Build under Agenda (This will trigger a process which may take a while)
4.5 Building Agendas in PennERA

5. Once the Agenda is Built click View under Agenda to open the document. A pop-up window will appear to show that the document is downloading.

Once you have the document open, save it to your computer, you will need to make edits to various sections including:

Adding meeting time:

Adding Page Numbers:

Deleting the Expedited Reviews:
Prior to converting the file to a PDF, review each Full board item (New Protocols, Continuing Reviews, Amendments, Other reviews) to ensure all data entry is present and correct, agenda notes appear and are legible, and each reviewer is appropriately assigned:

### New Protocols for Full Board Review

<table>
<thead>
<tr>
<th>825433</th>
<th>Space-time study of youth and school violence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal:</td>
<td>WIEBE, DOUGLAS J</td>
</tr>
<tr>
<td>Investigator:</td>
<td>NATIONAL INSTITUTE OF JUSTICE</td>
</tr>
<tr>
<td>Reviewer(s):</td>
<td>CURTIS, BRENDA L; HATFIELD, LINDA A</td>
</tr>
<tr>
<td>Agenda Notes:</td>
<td>Electronic Submission</td>
</tr>
<tr>
<td>Confirmation Code:</td>
<td>cbghjbe</td>
</tr>
</tbody>
</table>

**Reason for convened review:** This study has been assigned for convened review in order to assess study risk due to subject vulnerability (potentially disenfranchised youth, assault victims).

**Note:** This protocol will require a subpart D determination.

**Description:** We propose a mixed-methods study to understand risk and protective factors for school assault. Subjects will be males and females, 12-18 years, requiring treatment at the emergency department of CHOP or HUP for an assault-related injury. Subjects will be interviewed using portable GIS technology to recreate paths of their activities from the time they awoke in the morning up until the time they were assaulted.

**The following documents were included in this review:**
- HS-ERA Application Submission, confirmation code: cbghjbe, submitted 8-5-16
- Cover Letter (RfI: Initial Submission), dated 6-24-16

### Closing Agendas in PennERA:

Once a meeting has taken place, actions should no longer be assigned to that agenda. Since expedited assignments also get assigned to an agenda, it is important for the board admin to close agendas quickly after the meeting takes place so that new items don’t get sent to an agenda that has already been built.

To close an agenda:

1. Follow steps 1-3 for building an agenda shown above
2. On the meetings page click the number in blue text shown under Items for the agenda date you want to close

![Meetings Table]

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UPENN IRB
3. On the next screen check the box in the upper left corner “Close Agenda”. Then click Save. You will know the agenda is closed with the “Change Agenda” button in the upper right is greyed out. Then Click Close.

![Agendas for IRB #5 on 27-Mar-2019](image)

This agenda is now closed. IRB staff conducting reviews can no longer select this agenda date from the dropdown on the review details page for any open action in PennERA. Also the review details pages for all actions contained in this agenda will no longer be editable without re-opening the agenda.

To Re-open an agenda, follow the steps above, uncheck the “close agenda” box and save. When re-opening agendas, be sure to close them again as soon as possible.

**GUIDANCE**

- Agenda items are tracked by the Board administrator and coordinator in an Xcel spreadsheet on the G Drive for each board. It is wise to compare your agenda file to the contents of your tracker to ensure everything is present.
- Agendas should be finalized and sent out to the members about 10 days in advance of the meeting date
- If more items are added to your meeting after the main agenda goes out, you may be required to create an “Add On Agenda” which follows the same process above.
- Items that are missing from an agenda are usually not appearing because of incorrect data entry. If an item is missing, go to that action in PennERA, look at the Review Details page and ensure the correct Board #, Agenda Date, Review Level, and Pending determination are present.
OVERVIEW

IRB Determination Letters are the final step in the IRB review process. The Penn ERA system is equipped with various tools which pull study data directly into our letters therefore accurate communication of IRB decisions is reliant on accurate data entry. This section describes procedures for drafting all types of letters. The majority of submissions received by the IRB are electronically sent through the HSERA system and are discussed primarily. Paper submissions are also described in this section.

The Assigner may be an IRB Director or authorized designee. The Letter Drafter may be any member of the IRB staff. The Signer must be a Director or staff member at the administrator or senior administrator level who has been granted signatory authority by the Director.

All expedited submissions which receive an electronic decision in HSERA in a given day are populated on the Determination Letter Generation Report for assignment the following day. The Report is shared with the IRB Office manager, and IRB administrative support staff to determine the volume of letters to be distributed to each letter drafter as well as volume of letters to be distributed to each signer. Division of responsibility for drafting convened letters after a meeting is discussed in the Convened Assignment workflow.

All paper submissions which receive a decision are placed in a separate area on the signing desk to indicate they have received Final Approver signature and are ready to be assigned out for determination letters. Once the list of necessary letters is generated, the assignment process begins:

ASSIGNING PROCEDURES

1. The assigner utilizes the Assign to IRB admin section of HS-ERA to identify completed actions which need determination letters drafted
2. The assigner uses the assign field for the submission and adds a comment indicating who the letter is assigned to for drafting and who should sign the letter if signature is required.
3. Paper submissions are organized and assessed by the assigner. The assigner makes a physical note on the file detailing who the letter is assigned to for drafting and who should sign the letter if signature is required. The same assigning rules apply to paper as HSERA, however the letter will need to be printed and inserted into the physical file on top of the materials submitted for review.
4. For letters related to convened actions, please see the convened assignment workflow for details about assignment and responsibility for letter generation. Generally, the letter drafting procedures described in this section also apply to convened actions.

LETTER DRAFTING PROCEDURES

1. Letter drafters receive an Email alert that they have a letter assigned to them and the assignment appears in the HSERA Queue.
2. Each letter assignment is opened in both HSERA and PennERA by utilizing the Protocol number and confirmation code.
3. The letter drafter reviews the HSERA comments section including any attachments to gather necessary information for drafting the letter.
4. Using specific notes provided by the submission screener, data entry for the particular submission is completed in PennERA.
5. Any questions about determinations or data entry should be directed to the screener of the submission prior to finalizing the letter. Once the data entry is complete, the summary should be updated if appropriate. Please see the separate GDO section detailing proper summary update.
6. After completing data entry and summary updates, the letter drafter will build the letter using the letter build function on the review details page of PennERA. The PennERA system will generate a letter based on the chosen
4.6 Letter Drafting

A template that will include both template language regarding the determination and study specific information based on the completed data entry. See below for letter building instructions.

7. Depending on the type of letter generated, the draft may require formatting revisions and conversion to a PDF. These formatting revisions should be completed as needed.

8. Prior to placing letters for signature or uploading completed letters, any applicable consent forms that require IRB stamps should be appropriately attached. Please see the separate GDO section regarding Consent stamps.

9. Once a formatted letter is finalized and consents have been attached and stamped, it should be placed for signature if required. Letters that require signature should be placed in the designated folder for the specific IRB staff person on the Gdrive (G:\ELECTRONIC LETTERS\IRB Letters Not Signed). Signed letters will be returned to the letter drafter in their folder (also on the Gdrive -G:\ELECTRONIC LETTERS\IRB Letters Signed).

10. All finalized and signed letters should be distributed according to the study record:
   a. Electronic records should have finalized letters uploaded to the action in HSERA and to the attachments page in PennERA.
   b. Paper records should have finalized letters uploaded to attachments in PennERA and printed and placed in the physical file.

BUILDING LETTERS IN PENNERA

The process for building letters is the same for all letters regardless of review level or submission type. The only variation is the letter template chosen and the data entry required which should already be completed before the letter is drafted.

To build letters:

1. Log in to PennERA
2. Open the protocol you wish to draft a letter for using the protocol number
3. Open the submission you wish to draft a letter for
4. Ensure proper data entry is completed on the General Review page then navigate to the Review Details page
5. On the Review Details page, ensure all data entry has been completed and the summary has been updated appropriately
6. Scroll down to the Communications ribbon at the bottom of the Review Details page and click the radial button for “Build Letter”

7. Select the Document category first (always Penn IRB Determination Letter)
8. Select the Letter Template from the dropdown (template is dependent upon the type of submission and the determination)
9. Name your file. This file name will be attached to your letter and you will use it later to upload any signed versions to the attachments page. All IRB letter file names follow the same logic:
   - YEAR.MONTH.DAY-SUBMISSION TYPE-PI NAME-PROTOCOL#-LETTER DRAFTER INITIALS – Examples:
     - 2019.2.27-MOD-ZIOLEK-823100-ER (letter drafter initials are important when a letter requires signature so that the signer can return the letters to the appropriate staff)
     - 2019.3.14-CR-FALK-818626-MM
     - 2019.4.17-INITIAL-FREY-830978-TK
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4.6 Letter Drafting

- 2019.1.27-FBMOD.withheld-TANYI-837593-ER (FB indicates this was a letter from a convened meeting. withheld was added to make it clear that this review was not granted full approval and contains stipulations)
- Other indicators may be added to file names as long as the same general naming logic is also present

10. Click Build.
11. The file will appear in a list below the build button with several actions available:

<table>
<thead>
<tr>
<th>Document Name</th>
<th>Document Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019.3.7-TEST-ZIOLEK-823100-ER</td>
<td></td>
</tr>
</tbody>
</table>

12. The first action to take is to View the letter. This will open a pop-up window that shows you either a Word version of your letter to refine and convert to PDF OR will generate a PDF. Either way- save the letter to a letters folder on your computer since it will need to be placed in other locations
13. Once you have a copy saved to your computer, click Attachment under Move To. This move your letter to the Attachments page of PennERA.
14. This brings you to step 7 in the letter drafting process described above. Letters should then be finalized, signed and uploaded as appropriate.

Note- as of March 2019 the Move To: Email function is not operational but may be activated in the future.

SIGNATURE REQUIREMENTS
1. Signature requirements for IRB determination letters are assessed on a case by case basis. The decisions for signature requirements are made at the Director level for each review type. The PennERA letter templates are specifically formatted to indicate when signature is required
2. If the PennERA template being generated populates an area for signature at the bottom of the letter, a PDF electronic signature must be affixed by an IRB Director or Administrator / Senior Administrator who has been granted signatory authority by the IRB Director.
3. If the PennERA template does not include a signature area and ends with the statement- ***This letter constitutes official University of Pennsylvania IRB correspondence. *** -a signature is not likely to be required.

UPLOADING COMPLETED LETTERS TO HSERA

1. Log in to HS ERA and go to:
2. Open the letter you want to upload
3. Go to the document listing in the letter and copy the confirmation code from the document list
4.6 Letter Drafting

4. Paste the confirmation code into the confirmation code search bar in HSERA

5. Press Filter

6. Click the eyeglasses OR click Review on the far right

7. On the next screen in the top Right – click “Add Decision Document”

8. On the next screen use the drop-down menu to choose the appropriate determination

9. Click Browse to find and select the letter you are uploading from your computer

10. Click upload once you see the file name populate in HSERA

11. To confirm the letter uploaded appropriately you can check the “IRB Correspondence” section within the application to see if your letter is there or if you must do it again.

UPLOADING SIGNED LETTERS TO PENNERA

1. Log in to PennERA

2. Search for and open the protocol

3. From the summary page click “attachments” on the black ribbon menu

4. On the attachments page, click “Add” in the upper right corner

5. In the pop-up window select “version of an existing document”

6. Open the dropdown menu and find the letter you want to upload (based on the file name you gave to your letter when you drafted it)

7. Select your letter from the list

8. Click Choose File which will open a file browser window.

9. Navigate to the folder where your signed letters are stored and select the letter you want to upload

10. Click upload in the upper right corner of the PennERA pop up window. Wait for the upload to take place then click close.

11. When you are done, you will see that the letter on the attachments page will now have 2 in the versions column. Please note that letters which do not require signature do not require additional upload to PennERA. For those letters, the version you “send to attachments” during the letter drafting process may serve as the final version unless there are errors that needed to be corrected. If Any revisions are made to a letter after the first draft, a copy should be uploaded to PennERA. Adjustments to the data entry may also be required.
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4.7 Reliance Agreement Letters – Penn is Relying IRB

These instructions apply to drafting letters for initial review and subsequent modification of reliance agreements where Penn has ceded review to another IRB. These applications will NOT receive continuing review.

**Step 1: Before you begin data entry, assess the reviewer notes in HSERA**

To draft the letter, you will need to know:

- **Determination** – should it be acknowledged or approved-relying IRB? – these are the only two choices
- **The full official name of the IRB of Record** (Should not be CHOP – This is not for Penn/CHOP agreements)
- **Any notes that should be in the letter**
- **Document listing specifications** – in general we will NOT be listing documents for these unless specifically requested by the submitter
- **Approval and Expiration** dates from the central IRB approval letter (if available)

**Step 2: Start with the Summary page in PennERA**

The new letter template pulls a lot more information from Penn ERA than the other templates. As the letter drafter it is YOUR job to make sure the data entry is correct and complete BEFORE drafting the letter so that the letter is correct and complete. This letter template generates as a PDF so is more difficult to edit compared to the Word generated letters. Some information will already be in PennERA because it automatically fills in, or pulls from HSERA.

**The data entry at the top of the summary page should be completed as follows**

1. Review Category – Should be Reliance Agreement
2. Research Type – Can be blank
3. Risk Level – Can be blank
4. Reviewers – not needed
5. Determination – Should be Acknowledged or Approved-relying IRB – these are the only two choices
6. Board Name – Auto feed from HSERA
7. Determination Date
   a. If acknowledged status – should be date the acknowledged button was pressed in HS-ERA
   b. If approved relying IRB status – should be the approval date on the central IRB approval letter
8. Approved From and Approved to Dates
   a. If acknowledged status – should be blank
   b. If approved relying IRB status – should be the dates in the central IRB approval letter
9. **Scroll Down to “Other Information” section of the Summary Page for additional data entry:**
   a. IRB Authorization Agreement – “External IRB of Record” checkbox should be checked
   b. Name of Institution(s)/Comments – text box should include the official name of the Central IRB (Only the name – not a sentence). No spaces before or after the text. This will impact formatting of the letter.

Click Save once the data entry on the Summary page is complete. Then go to Submissions page and choose the appropriate action.
Step 3: Begin data entry on the General Review Page (first review page where agenda notes are entered)

1. Submission number should be the confirmation code from HSERA
2. Submit Date should be the same as Created On Date
3. Coordinator field is blank
4. Review type should be Review - Administrative Action OR Amendment
5. Do not fill in Exempt or Expedited categories
6. Do not fill in review activities
7. Description field data entry should be completed as:
   - Electronic submission
   - Purpose: or Modification Summary:
   - The documents included with the application noted below are acknowledged:
     - HSERA Reliance Agreement Application, confirmation code:xxxxx, submitted

Click Save once the data entry on this page is complete before moving on to the next page.

Step 4: Continue data entry on the Review Details Page (second review page where determination is entered and letter is drafted)

1. Review Method is still IRB Review
2. Review Category is Reliance Agreement
3. Board should match HSERA
4. Agenda should be YES
5. Agenda Date should always be in the future
6. Review/meeting date should be date acknowledged in HSERA
7. Determination is ALWAYS ACKNOWLEDGED even if HSERA says approved, Even if the summary page says Approved relying IRB
8. Risk Level should be blank
9. Determination Date should match review date in HSERA
10. Date From and Date To should be blank
11. DO NOT USE THE UPDATE SUMMARY BUTTON UNLESS THERE HAS BEEN A CHANGE TO PERSONNEL.

Step 5: Building the Letter on the Review Details Page

1. Determination comments should include the document list from the agenda notes page as well as any notes instructed by the screener
   - Example note: “Note: please submit a modification via HSERA to provide the finalized IRB Authorization Agreement signed by the IRB of record, the approval letter from the IRB of record, and a stamped copy of the informed consent form as soon as they become available.”
2. Provisions should be blank
3. Set the font to Times New Roman
4. Set font size to #3
5. Save the data before building the letter
6. Click the Build Letter radial button
7. Choose Penn RIB Determination Letter
8. Choose the HS Reliance Agreement Template
9. Name your letter appropriately
10. Click Build
11. Once the PDF has opened on your desktop, please check to make sure all fields in the letter are filled in appropriately (PI name, CC names should match the Study Contacts in HSERA, all dates and notes ETC...). Once you are sure the letter looks the way it should, save it to your local folder as you normally would and upload to HSERA and Penn ERA. These letters do NOT require signature.
OVERVIEW
All informed consent forms for expedited and convened protocols require an IRB approval stamp. Standalone HIPAA authorization forms and Information Sheets that contain the elements of consent but do not obtain documented consent (a physical signature) from subjects do not require an approval stamp. This section details the process for stamping informed consent forms and determining dates of approval.

PROCEDURES FOR DETERMINING STAMP
During Screening, the IRB staff will determine if the following conditions apply:

- the informed consent form has designated signatory line for the participant/subject and/or legally authorized representative
- the protocol is currently enrolling, the protocol requires for subject(s) to be re-consented, or the protocol requires for subject(s) to be consented despite a closed enrollment status
- the informed consent form is the most up-to-date version
- the protocol is currently approved

The Screener will then document in the checklist whether it is appropriate for stamped consents to be released. The Letter drafter should refer to the written instructions from the screener regarding whether consent forms should be stamped or not. Withholding a stamped consent form often occurs if a protocol receives a Tabled, Withheld, administratively finalized or Contract pending determination.

The IRB only provides a digital stamp on an informed consent form. In no other case may a digital stamp be provided on any other protocol documents. Protocols conditionally re-approved or withheld do not receive stamped informed consent form(s) with the IRB decision letter.

Combined Informed Consent and HIPAA Authorization Forms
Informed consent forms combined with HIPAA authorizations are to be included in the procedures for digital stamping (such documents are usually titled “Informed Consent and HIPAA Authorization Form). All references to informed consent forms may include those combined with HIPAA authorization forms. However, standalone HIPAA authorization forms do not get stamped in any case.

PROCEDURES FOR DIGITAL STAMPING
The informed consent form may be submitted as a Microsoft Word document, paper document, or an Adobe PDF. Any previously affixed approval stamps should be removed prior to adding a new approval stamp. This is commonly referenced as a “clean consent.” If the informed consent form has approval stamp from another IRB and the consent form requires a stamp form the Penn IRB, the consent form is stamped.

Informed consent forms in a Microsoft Word format are converted into a PDF. Informed consent forms as a paper documents are scanned into a PDF.

A PDF version of the informed consent form accompanies a PDF version of an IRB decision letter. The PDF informed consent form is attached below the PDF IRB decision letter by using Adobe Acrobat.

A protocol may have multiple informed consent forms. All informed consent forms receive the same stamp unless directed otherwise by IRB Administrator.

The informed consent form(s) are given a digital stamp by using the Adobe Acrobat Add Watermark function.

PROCEDURES FOR FORMATTING, DETERMINING APPROVAL PERIOD, AND SPECIAL CONDITIONS
Determining the Approval Period for Stamping

The IRB Administrative Assistant uses the Adobe “Watermark” tool for inserting the digital stamp. The primary function of the stamp is to state informed consent form’s approval period and may also indicate if there are any conditions on the usage of the form. The text of stamp should state the approval period from the initial date of the submission’s approval to the date of the protocol’s expiration. The approval period is dependent on the submission type and level of review. The approval period will fall into one of the following conditions:

1. If the informed consent form is approved with an expedited/full continuing review, the approval period will start the date of the expedited protocol’s approval and end 364 days later. The expiration date is the last date that the protocol is approved through.
2. If the informed consent form is approved with an expedited/full modification, the approval period will start the date of the protocol’s approval and ends the day protocol is set to expire.
3. If the informed consent form is approved with a response an initial withheld review, the approval period will start the date of the protocol’s approval and end 364 days later from the initial withheld date.
4. If the IRB approves research with conditions, date of approval is the date that the conditions were determined to be met.

The stamp font should be Monotype Corsiva Italic and no larger than 12 point. The stamp should be placed on every page of the consent form and not cover or obscure any of the document’s existing text. The stamp should not appear on the determination letter.

Typically, the stamp is placed in the footer in the form. Example:

For a study that includes an expiration date the following stamp date formats are appropriate:

- IRB Approved From: 06-01-2018 To: 05-31-2019
- IRB Approved From: 01-Jun-2018 To: 31-May-2019

For a study that does not expire the following stamp date formats are appropriate:

- IRB Approved: 06-01-2018
- IRB Approved: 01-Jun-2018

Regardless of what date format is chosen, please be consistent.

Special Conditions

The IRB Administrative Assistant may be instructed to stamp an informed consent form when (1) the consent form is intended for re-consent purposes only or (2) the consent form is intended for a one-time use by the protocol site. The Administrative Assistant may consult the appropriate IRB Administrator for assistance when one of these conditions may apply.

(1) Special Condition: One-time use only

If an informed consent form will be used for only a single subject (such as a short form), the stamp should reflect the consent form’s one-time use as shown below.

ONE-TIME USE ONLY
IRB Approved From: 06-01-2012 To: 05-31-2013
UNIT 4 – SYSTEMS, DATA ENTRY, COMMUNICATIONS
4.8 Stamping Informed Consent Forms / Determining Dates of Approval

(2) Special Condition: Re-consenting
If an informed consent form is intended for only the re-consenting of subjects, the stamp should reflect the consent form’s one-time use as shown below.

FOR RE-CONSENT ONLY
IRB Approved From: 06-01-2012 To: 05-31-2013

The following list references the different types of informed consent documents that typically require a digital stamp on the PDF converted protocol document:

- Informed Consent Form
- Combined Informed Consent and HIPAA Authorization Form
- Parental Permission Form
- Parental Permission and HIPAA Authorization Form
- Assent Form
- Consent Form – Short Form
- Addendum to Informed Consent Form

SCENARIOS FOR DETERMINING DATES OF APPROVAL AND EXPIRATION
Initial approval of a study is granted on the date the first approval (Approved or Withheld Approval) is granted. Initial approval may be complicated by complex issues that prevent an approval determination from being made. Expiration is always 364 days later unless the board determines continuing review should be required every 6 months. Only a Continuing Review can change the approval and expiration date of a study. After Continuing review, the Approval date is the date the IRB granted Approval of the Continuing Review, expiration is 364 days later.

Scenario 1: The IRB reviews and approves a study for one year, without any conditions, at a convened meeting on October 1, 2013. The date of IRB approval is October 1, 2013 and the date of IRB expiration is September 30, 2014.

Scenario 2: The IRB reviews a study at a convened meeting on October 1, 2013, and approves the study for one year, pending a response to directive stipulations that the IRB chair or his or her designee can verify which requires a response submission (i.e. Withheld Approval). On October 31, 2013, the IRB chair or designee confirms that the required minor changes were made and approves the response. The date of approval is October 31, 2013 but the date of expiration is still September 30, 2014. Continuing review must occur within 365 days of the original review approval (even if the approval had directive stipulations).

Scenario 3: The IRB reviews a study at a convened meeting on October 1, 2013 and has serious concerns or lacks significant information that requires IRB review of the study at subsequent convened meetings (i.e. Tabled or Disapproved). That determination resulted in another convened review on November 3, 2013 and again on December 5, 2013. On December 5, 2013, the IRB completes its review and grants approval to the study for one year. The date of IRB approval is December 5, 2014 and the date of expiration is December 4, 2013.

In Scenario 3 even though reviews took place on October 1 and November 3 – no type of approval was granted therefor those dates cannot be used to establish the approval period.

Scenario 4: The IRB reviews and approves a study via expedited continuing review on October 1, 2013. The informed consent form is approved with an approval period that starts October 1, 2013 and ends September 30, 2014.

Scenario 5: The IRB reviews and approves a modification to a protocol on October 1, 2013. The most recent continuing review was conducted on February 1, 2013. The informed consent form is approved with an approval period that starts on October 1, 2013 and ends January 31, 2014.
# UNIT 5

## EXPEDITED IRB REVIEW PROCEDURES

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<th>5.0 Expedited Assignment Workflow</th>
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<td>5.2 Initial review Exempt Research &amp; Limited IRB Review</td>
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<tr>
<td>5.3 Initial Review Prime / Umbrella Grant / Just In Time (JIT) Review</td>
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<td>5.4 Initial Review Expedited Research Review</td>
</tr>
<tr>
<td>5.5 Expanded Access (Single Patient, Emergency, Compassionate Use, Humanitarian Use)</td>
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<td>5.6 Continuing Reviews Eligible for Expedited Review</td>
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<td>5.8 Deviation Submissions</td>
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<td>5.10 Reportable Adverse Events Submissions</td>
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<td>5.11 Expedited Responses to Convened Review</td>
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<td>5.12 Closure Submissions</td>
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</tbody>
</table>

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5.0 – Expedited Assignment Workflow

Overview

This section describes the workflow for all actions received by the IRB that do not require convened review. Actions that require convened review are discussed in a separate GDO section. The majority of submissions received by the IRB are electronically sent through the HSERA system. Paper submissions are also described in this section. This process applies to Initial, Modification, Continuing Review, Deviation, Exception, and Reportable Events that do not require convened review. The Assigner may be an IRB Director or authorized designee. The Screener may be any IRB staff member (including IRB Directors). For any submission that qualifies as research, the Final Reviewer must be one of the IRB Directors or an IRB Board Chairperson.

1. Receipt
   a. The submission is received in the HS-ERA IRB queue once approved by the Principal Investigator and Department Chair as required.
      i. All initial submissions require both PI and Dept. Chair approval prior to IRB receipt
      ii. Any subsequent submissions require only PI approval prior to IRB receipt (response to initial, modification, continuing review, exception, deviation)
      iii. Submissions returned by the IRB to the study team via HSERA using either “return for response without approval” or “return for revision without approval” do not require PI approval or Chair approval when the response/revision is re-submitted
   b. Upon receipt in the IRB queue, the status of the submission is automatically changed from “Pending review by (Principal Investigator’s or Department Chair’s name)” to “Accepted and submitted for review”.
   c. Paper submissions are received by the front desk staff. The submission is manually added to PennERA by front desk staff by utilizing the Add New field in the submissions page or by creating a new protocol and updates the review activities page to reflect the receipt of the submission. The documents provided by the submitter are date stamped and grouped with the most recent study file folder and placed on the assigning desk
   d. Email Submissions – Generally the IRB does not have a mechanism for receiving emailed submissions (there are few exceptions). If a study team reaches out to an individual member of the staff and arranges for submission of a single action via email this may be accepted.
      i. If the emailed submission received is for a study that is documented on paper, the contents will be printed, stored with the file and processed as if it were received via traditional mail or drop off. Contents of email submissions may also be uploaded to PennERA as attachments for documentation.
      ii. If the emailed submission received is for a study that is documented in HSERA, the IRB may process it and require a follow up HSERA submission to complete the regulatory file. Contents of email submissions may also be uploaded to PennERA as attachments for documentation.

2. Assigning
   a. The assigner utilizes the Assign to IRB admin section of HS-ERA and sorts submissions by Status so that all submissions with an “accepted and submitted for review” status appear first.
   b. The assigner identifies incoming actions and makes a determination based on the information provided by the study team as to whether the action requires convened review or can be reviewed expedited.
c. Actions that qualify for expedited review are assigned to a screener with appropriate expertise for screening the particular submission.

d. The assigner uses the assign field for the submission and adds a comment to the submission detailing the type of submission and any deadlines for review.

   i. It is at this time that the assigner should alert the screener that a submission can be reviewed expedited or request that the screener assist with assessing level of review required.

   ii. It is not uncommon for a submission assigned for expedited review to be referred for convened review based on thorough assessment of content. It is ultimately the screener's responsibility to verify level of review required.

e. Paper submissions gathered on the assigning desk are organized and assessed by the assigner. The assigner applies the same scrutiny to paper study documents to determine level of review required as needed for HSERA assignments. The assigner makes a physical note on the file detailing the type of submission and any deadlines for review. The same assigning rules apply to paper as HSERA, however the documentation for the submission will be only on paper and grouped with the physical file. The file is then placed on the desk of the IRB staff person who is assigned to process it.

3. Screening

a. The screener receives a notification email detailing the assignment and deadline for completion and locates the submission in HS-ERA by utilizing the protocol number and confirmation code.

b. The screener then conducts a thorough screening of the action by utilizing the appropriate submission screening checklist. Specific information about submission screening is discussed in other sections of the GDO.

c. If no issues were noted during the screening or if the issues raised by the screener have been resolved, then the submission is assigned to the appropriate board in HSERA to electronically create an action in the PennERA system

   i. If concerns are raised, responses from the study team should either be received via email prior to placing the submission for approval or the submission should be returned for revision. Steps for appropriately returning submissions are described elsewhere in the GDO.

d. Once the action appears in the Submissions page of PennERA, the screener must complete any necessary data entry to assign a final reviewer in PennERA

   i. If the final reviewer will be an IRB Board Chairperson it is expected that the screener will email the chairperson with relevant attachments for convenience in conducting the review.

   ii. When assigning to a Board Chair, selection should be based on appropriate expertise.

e. Paper submissions are placed on the screener’s desk area by the assigner. The screener conducts a thorough screening utilizing the appropriate submission screening checklist. A copy of the finalized checklist and any emails are printed and attached to the study file. When ready for final review, the screener places the file on the signing desk in the IRB office. The same screening rules apply to paper as HSERA, however the documentation for the submission will be only on paper and grouped with the physical file.

4. Final Review

a. The Final Approver finds the submission in HS-ERA by opening the My Submission Approvals – view assigned section. The Final Approver reviews the application to determine if the criteria for expedited
approval have been met. If any questions or concerns related to the criteria for approval are identified, the approver communicates these issues to the screener.

b. If no concerns are raised or the issues raised by the Final Approver are appropriately addressed, the Final Approver then approves the submission in My Submissions Approvals – view assigned section by submitting a decision for this protocol.

c. If final review is assigned to an IRB Board Chairperson, the Chairperson may either document their approval electronically in HSERA OR respond with their approval via email. If IRB Board Chair decision is received via email, the HSERA submission should then be routed to an IRB director to document the Chairperson’s decision in the system electronically.

d. Paper submissions are placed on the signing desk for final approval. A physical signature from an IRB director is required for documenting approval of a paper submission. The same final approval rules apply to paper as HSERA, however the documentation for the submission will be only on paper and grouped with the physical file.

e. The final reviewer may raise additional issues upon review. In these situations, the IRB Chair or Director will not log a decision in HSERA. Instead they will contact the screener via email to communicate issues that should be brought to the study team. The screener should then either contact the study team via email to resolve the issue or return the submission for revision. If a submission is returned, the PennERA data entry should be updated to remove the assigned reviewer and change the determination to Issue Identified.

f. Final Approver for expedited submission should be chosen accordingly:

- Response to initial withheld approval: Primary: Board Chair/Back-up: Regulatory representative present at the meeting
- Response to conditional re-approval: Primary: Board Chair /Back-up: TAZ/PAS/DAH
- Response to withheld approval modification: Board Chair /Back-up: TAZ/PAS/DAH
- Initial biomedical exempt: Primary: DAH/Back-up: TAZ
- Initial SBS exempt: Primary: DAH/Back-up: TAZ
- Initial biomedical expedited (any category but 5 with waiver request): Primary: TAZ/Back-up: DAH
- Initial biomedical expedited (category 5 with waiver request): Primary DAH/Back-up: TAZ
- Initial SBS expedited: Primary: DAH/Back-up: TAZ
- NHSR research: PAS/Back-up: TAZ/DAH – reviewer in PennERA may reflect the screening Analyst
- Expedited CR (all categories but exceptions, see below): Primary: PAS/Back-up: TAZ/DAH
- Expedited CR (any category 5): Primary: DAH/Back-up: TAZ
- Expedited CR (categories 8 and 9): Primary: PAS/Back-up: DAH/TAZ/Board Chair as appropriate
- Expedited modification for expedited study (not category 5): Primary: PAS/Back-up: DAH/TAZ
- Expedited modification for expedited study (category 5): Primary: DAH/Back-up: TAZ
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES
5.0 – Expedited Assignment Workflow

- Expedited modification for convened study: Primary: TAZ/Back-up: Board Chair as appropriate
- Deviation for expedited study (categories 1-7, see below for HIPAA deviations): Primary: TAZ Back-up: DAH
- Deviation for convened study including categories 8,9 (not impacting subject safety or data integrity): Primary: TAZ/Back-up: Chair
- Deviation (potential impact on subject safety or data integrity): Primary: Board Chair Back-up: TAZ
- HIPAA Deviation: DAH/Back-up: TAZ
- Exception (medical content): Board Chair
- Exception (logistical content): TAZ/Backup: DAH
- Reportable event (not meeting IRB reporting criteria): TAZ
- Reportable event (meeting IRB reporting criteria): Board Chair
- Privacy board determinations (preparatory to research, public health surveillance): DAH
- Personnel changes: Primary: PAS/Back-up: TAZ/DAH
- Administrative updates: Primary: PAS/Back-up: DAH/TAZ
- Completions: Primary: PAS/Back-up: DAH/TAZ
- Authorization agreements: TAZ/Back-up: PAS
- CHOP/Penn agreements: TAZ/Back-up: PAS
- Individual Investigator agreements: TAZ
- Conflict of interest notifications or revisions: DAH/Back-up: TAZ

Note: Expedited submissions that are assessed to either have a potential impact on subject safety or require a scientific assessment to determine that continuing approval should be granted will be reviewed either by a scientific IRB member or physician scientist member, when necessary. If a submission has both a scientific IRB member reviewer and a physician scientist as consult, this will be documented by selecting two reviewers for the expedited action.

Examples of types of actions and appropriate reviewers include:

- **Deviations with a potential impact on subject safety**
  - **Require review by an IRB Chair or appropriate IRB physician scientist member**

- **Exceptions that have the potential to pose greater than minimal risk and are eligible for expedited review per SOP section 3.3.1.**
  - **Require review by an IRB Chair or appropriate IRB physician scientist member**

- **Potential Unanticipated Problems that meet IRB reporting criteria (unexpected and related events)**
  - **Require review by an IRB Chair or appropriate IRB physician scientist member**
5.0 – Expedited Assignment Workflow

- Modifications to Greater than Minimal Risk protocols that have a potential implication for subject safety (i.e. new safety data)
  - Require review by an IRB Chair or appropriate IRB physician scientist member

Expedited submissions that do not meet the criteria listed above will be assigned to scientific and non-scientific IRB members. Member assignments are based on the content of the submission and the expertise of the IRB members.

5. Determination Letter

a. All submissions which receive an electronic decision in HSERA in a given day are populated on the Determination Letter Generation Report for assignment the following day

b. All paper submissions which receive a decision are placed in a separate area on the signing desk to indicate they have received Final Approver signature and are ready to be assigned out for determination letters.

c. The workflow for Letter Drafting is fully described in a separate section of the GDO

6. Paper submissions and Review Activities

a. Reviews for paper protocols are captured in PennERA just like HSERA reviews. However, HSERA can capture the progress of a submission through the workflow described above with various timestamps. For paper submissions HSERA cannot capture the workflow so IRB staff must manually document the workflow in PennERA by utilizing the Review Activities function.

b. The Review Activities function is available on the Agenda notes review page:
c. During every step of the workflow outlined in the pages above, the IRB staff should open review activities by clicking SET, choose a status, make relevant comments and click Save. The review activities will then document a series of notes with date, time and user to track the progress of the assignment.
OVERVIEW

Activities that do not meet the HHS and FDA definitions of human subject research do not require submission to the IRB. However, investigators may need assistance in making an official determination as to whether a submission meets the definition. This section describes procedures and guidance for screening and documenting determinations of QI projects and Not Human Subjects Research.

QI REVIEW PROCEDURES

The IRB has a designated email inbox for the research community to submit QI projects for optional IRB assessment - qiirb@upenn.edu. The details of the QI inbox management are discussed in a separate GDO section. QI projects may be received via the email inbox or may come through HSERA as Exempt, Expedited or Full applications. The workflow process for QI submissions received via HSERA follow the same workflow process as other expedited submissions described in GDO section 4.1. Other potential workflows are described below.

Upon receipt of a QI project submission, the screener should first determine whether the project is a Quality Improvement (QI)/Program Evaluation or if it is Research. The submitted documents should be reviewed to assess the goals, methods and design:

<table>
<thead>
<tr>
<th>Goals</th>
<th>Research</th>
<th>Program Evaluation (PE)/QA/QI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Seeks to &quot;prove&quot;</td>
<td>1. Benefit a specific program</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Seeks to improve</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Does it work?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Does it do what it was designed to do?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• How well does it work?</td>
</tr>
<tr>
<td>Methods</td>
<td>Involves experimental procedures or non-standard interventions</td>
<td>Does not involve experimental procedures or nonstandard interventions</td>
</tr>
<tr>
<td>Design</td>
<td>Objective in order to contribute to generalizable knowledge</td>
<td>Subjective: Although PE can be generalizable in theory, it's more subjective</td>
</tr>
</tbody>
</table>

The screener will pose any necessary questions and request any necessary documentation. The screener will forward the form and any correspondence to senior leadership for concurrence. If concurrence is received from at least two other staff members, the screener may inform the requestor that the project qualifies as QI. The determination will be communicated via email only to the individual who sent the request, unless a letter is specifically requested. If the request is determined to be research, the requestor is instructed via email to submit an HSERA application for review.

QI PROJECT GUIDANCE

General Attributes Of Quality Improvement Projects That Most Likely ARE NOT Research:
• Designed to help Penn comply or meet a recognized, evidence-based standard of care.
• Assess the performance of Penn and compare to national standards.
• Designed to solve a local problem, and the results of the project are expected to produce knowledge that is locally important but is not generalizable (universally applicable to institutions outside Penn).
• Uses an iterative design which changes quickly as results come in (i.e. Plan-Do-See-Act Cycle).
• Typically, would still be performed even if the project team knew that no professional recognition would result.
• The project would meet the FDA’s definition of human research:
  o The project involves the administration of an approved or experimental FDA regulated product directed by the protocol, NOT by standard medical practice.
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES
5.1 INITIAL REVIEW – QI Projects & Non-Human Subjects Research

- Specimens are being used to test the effectiveness or validate a medical device and the information is being submitted to the FDA for marketing approval or clearance
- An invalidated medical device is being used to guide patient care.

General attributes of Quality Improvement Projects that most likely ARE research needing IRB approval:
- The majority of patients involved are not expected to benefit directly from the knowledge to be gained
- Projects designed to randomize patients to a clinical intervention to assess the safety or efficacy of the intervention
- Multi-center projects which involve collecting data from other national/international sites to create treatment guidelines or other types of generalizable (universally applicable) knowledge
- Projects designed to advance the scientific literature
- Projects designed to advance the clinical care of patients at all hospitals in the United States (not just facilities at Penn)
- Projects designed to develop new national practice benchmarks.
- Typically would NOT be performed if the project team knew that no professional recognition would result.

Potential Review Questions

Questions about Student Involvement
- Is this project being implemented to meet any educational requirements on the part of the student? If so, please describe.
- Please confirm that the student will be on boarded as an official volunteer and trained in HIPAA compliance.

Questions about HIPAA
- Will identifiable data be used? If so, how will it be protected?
- Please confirm PHI will be stored securely on the Penn Medicine network drive

Questions about Design/Intervention
- How does the QI intervention differ from what is currently being done?
- How will this activity improve the quality of patient care? / Can you expand upon why the intervention would lead to improvements in the quality of patient care?
- It seems like this could also lead to generalizable knowledge and will thus advance scientific literature. Therefore, please clarify why you are submitting as QI over research.

Template Emails

If determined to be research Send an email to the study team with the following message, and cc the QI inbox (qiirb@upenn.edu):

Hello,
We reviewed your application for the project entitled: ______ and determined that the proposed project meets the definition of a human research because:
GIVE REASON(S)
Please submit a formal application via the HS-ERA online application. Submission guidance is available online here: https://irb.upenn.edu/initial. If you have questions after reviewing this, please feel free to contact us.

If QI and no request for a letter: Send the following email from the QI Box, qiirb@upenn.edu and cc the QI inbox

Hello,
It was determined that this project entitled: ______ qualifies as a quality improvement initiative that does not meet the definition of human subjects’ research and therefore further IRB review is not required. This email should suffice as your documentation. Please save a copy of it for your records. NOTE: Changes to the purpose, methods, or design of this project may alter the QI status and may require re-review.
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES
5.1 INITIAL REVIEW – QI Projects & Non-Human Subjects Research

DOCUMENTATION OF QI REVIEW CONDUCTED VIA EMAIL

All requests for QI review are documented in the QI Project Tracker located in G:\IRB\QI Projects. Each project should be identified as either QI or Research. Upon completion of any QI reviews, instructions for documentation will be emailed to a trained assistant or coordinator.

If the QI review was received via HSERA or Paper, the Letter generation process will follow the expedited letters workflow described elsewhere in the GDO. If the QI Review was received via email and a letter needs to be generated, the reviewer should forward the QI application to an IRB assistant or coordinator with appropriate training and request that they follow the GDO guidance for documenting and generating a letter for review.

Template email:
Hello,
Please see the attachments which require generation of a QI project letter. Please document this in the QI project tracker on the GDrive. Please follow the instructions in the GDO for NHSR/QI reviews to create a protocol in PennERA, upload the attachments and generate a letter to be forwarded to the study team.
Determination date in Penn ERA should be —
The Reviewer should be set as (name person)
Please contact me with any questions.

NHSR REVIEW PROCEDURES

A request for a determination of whether a project meets the definition of human subjects research can be received through various mechanisms (HSERA, IRB PO Box, etc.). When a request is received via email, the email recipient should inform the requestor that they should complete the human subject’s research determination form, if not attached to the email. The email recipient should refer the requestor to a senior IRB analyst, if they require confirmation of the determination after completing the form. The workflow process for NHSR submissions received via HSERA follow the same workflow process as other expedited submissions described in a GDO section 4.1. Other potential workflows are described below.

If the requestor requires confirmation of NHSR status, the screener will review the form. The screener will pose any necessary questions and request additional documentation if needed. The screener will forward the form and any correspondence to senior leadership for concurrence.

- If concurrence is received from at least one other staff member, the screener may inform the requestor that the project does not meet the definition of human subject’s research.
- If the screeners determine the project meets the HHS or FDA definitions of human subjects’ research, the screener should inform the requestor, and request they submit an application in HSERA. The NHSR application is insufficient for exempt, expedited, and convened review.

If a request is submitted in HSERA, the IRB Analyst conducts the initial review examining the HS-ERA application and any submitted study documents to determine if the application meets the HHS or FDA definitions of human subjects’ research. The screener will pose any necessary questions and requests any necessary documentation.

If the IRB Analyst determines the project does not meet the definition of human subject’s research, the submission will be forwarded in HSERA for final review.

If the IRB Analyst determines that the study meets either the HHS or FDA definition of human subjects’ research, the review process for exempt, expedited, or convened review should be followed as applicable.

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5.1 INITIAL REVIEW – QI Projects & Non-Human Subjects Research

NHSR GUIDANCE:

Possible review questions:

1. Are you receiving data/samples that contains any identifiers, including any of the following?
   - Geographic Identifiers such as City/Town OR Zip Code
   - All elements of dates (e.g. month/day, month/year, month/day/year) directly related to an individual (e.g., date of birth/death/admission/discharge, etc.)
   - Ages over 89 that are not aggregated into a single category of age 90 or older
   - Any other unique identifying number, characteristic or code (including the ID code assigned to the specimen on the original study)

2. Please provide a copy of the agreement that prohibiting the release of the key to you

3. Please provide documentation of the written policies and operating procedures from the repository or data management center that prohibits the release of the key to you.

The determination will be communicated to the individual who sent the request via email, unless a letter is specifically requested.

Template Emails

If determined to be research: Send an email to the study team with the following message:

Hello,
We reviewed your application and determined that the proposed project meets the definition of a human research because:
GIVE REASON(S)
Please submit a formal application via the HS-ERA online application. Submission guidance is available online here: https://irb.upenn.edu/initial. If you have questions after reviewing this, please feel free to contact me.

If NHSR and no request for a letter: Send the following email

Hello,
It was determined that this project ______ does not meet the definition of human subjects’ research and therefore further IRB review is not required.
This email should suffice as your documentation. Please save a copy of it for your records.

Letter Generation Instructions

Forward the application to an IRB administrative assistant or coordinator with the following email message:

Template email:
Hello,
Please see the attachments which require generation of an NHSR project letter. Please update the QI tracker on the G Drive and follow the instructions in the GDO for NHSR/QI reviews to create a protocol in PennERA, upload the attachments and generate a letter to be forwarded to the study team.
This project is (not research or not human subjects (choose 1).
Determination date in Penn ERA should be –
The Reviewer should be set as (name person)
Please contact me with any questions.
DOCUMENTATION OF QI & NHSR REVIEWS:
- All NHSR or QI applications received via email should be archived in the QI box archive folder. Any related correspondence should also be archived in this mailbox.

- Any NHSR or QI applications received via email with a request for a letter should have all submitted documents compiled and uploaded as PennERA attachments. They should be attached as either Protocol Documents or Supporting Documents.

- All QI projects regardless of method of receipt are logged in a QI tracker on the G:Drive.

- For any NHSR or QI applications received via HSERA:
  - Comments should be added to HSERA to provide the completed Human Subjects Determination worksheet and letter drafting instructions.
  - Comments should be added to HSERA to provide any email correspondence related to the review and any documents related to the review received from the study team outside of HSERA.
  - Text only comments regarding details of the review may be added at the reviewer’s discretion.
  - These should be assigned to IRB 7 when feeding the submission over to PennERA.
  - Assignment to PennERA should occur as soon as possible for all Initial submissions to ensure the ancillary review items on the HRPP page are sent out. If the first submission is returned, the PennERA determination for that action should be set to “Issue Identified”. Any subsequent returned submissions that appear in PennERA should also be set to “Issue Identified”. Only the submission which is assigned for final approval should reflect a “Pending status”.

PennERA Data Entry Requirements: If the request is received via email, the letter generator will be required to create a new protocol in PennERA. If received in HSERA, the action will already exist in PennERA for data entry completion.

To create a new Protocol:

1. Log in to PennERA and click “Create New” in the menu on the left side of the screen.
3. Fill in the title using the document forwarded from the reviewer and click continue.
4. Select a PI based on the documents forwarded from the reviewer and click continue.
5. In the new window that opens, navigate to the Summaries Page.
6. Click Sponsors in the menu on the left and click Add. Set the sponsor to “No Sponsor Number” unless the documents sent from the reviewer indicate a specific sponsor.
7. Navigate back to the Summary Page and follow the instructions below which are universal for all NHSR and QI projects that come from HSERA or Email.
Summary Page: The following data entry should always be completed on the Penn ERA summary page:
- Submission date, Original meeting date and determination date are always required and are the same date
- Review category is always administrative
- Determination is always Not Human Subjects Research (DO NOT PUT ACKNOWLEDGED ON THE SUMMARY)

General Review Page: The following data entry should be completed on the General Review page for the Initial review submission

This action does not get assigned to an agenda so data entry here is not needed
Review Details Page: The following data entry should be completed before drafting the letter:

![Administrative Review Details]

It is best to set the summary page manually to the appropriate data first. Then when completing the Review details page, you won’t use the update summary button. This is important because the determinations are different.

**Determination letter:**

**If NHSR:**
After receiving assignment to draft NHSR letter, please ensure all PennERA data entry is completed appropriately. Please Draft a letter using the “Not Research” Template in Penn ERA. Be sure to edit the letter to indicate which scenario applies (Not Research or Not Human Subjects). Any questions should be directed toward the submission screener. This letter template requires an admin PDF Signature.

**IF QI:**
After receiving the request to draft a letter, please ensure all PennERA data entry is completed appropriately as shown above. Please draft a letter using the “Quality Initiative” letter template in PennERA. Any questions should be directed toward the submission screener. This letter template requires an admin PDF Signature.
OVERVIEW
Experienced IRB staff review protocols to determine if they meet the regulatory and institutional criteria for exemption from IRB review. The workflow of Exempt Initial reviews follows the Workflow for Expedited Review procedures outlined in a separate GDO section. This section includes procedures and guidance for conducting Exempt reviews including Limited IRB review.

PROCEDURES
After receipt of the assignment and prompt assignment to PennERA, the Screener conducts the initial review examining the HS-ERA application and any submitted study documents to determine if the application meets the criteria for exemption from IRB review. During the screening process, the screener reviews and completes each required field of the IRB Initial Exempt Checklist to document the review and to ensure complete and consistent application of the exemption regulations, limited IRB review requirements (if applicable) and institutional requirements. Please refer to the Exempt Checklist for complete details and information regarding criteria for approval of an exempt protocol.

Any issues or concerns with the application or study documents (or lack thereof) affecting the criteria for exemption should be noted within the checklist or other screening document. Upon completion of the screening, the issues identified should either be addressed by the study team via email or the submission should be returned for corrections. Minor issues that do not require immediate action may be communicated to the study team via notes in the determination letter.

If the screener determines that the study does not qualify as exempt and requires expedited review, they should continue to process this submission according to the procedures for expedited review and begin using the Initial Expedited Checklist. If applicable, the electronic submission may be returned to the submitter to complete additional required sections that auto-populate for expedited applications. If convened IRB review is required, the submission will be returned to the study team to provide any additional information or documentation needed for the convened review. Procedures for returning submissions are described in a separate section of the GDO.

DOCUMENTATION OF THE REVIEW
HSERA
- Comments should be added to HSERA to provide the completed Initial Exempt Checklist with reviewer notes and letter drafting instructions
- Comments should be added to HSERA to provide any email correspondence or other review documents related to the review and any documents related to the review received from the study team outside of HSERA
- Text only comments regarding details of the review may be added at the reviewer’s discretion.
- All Exempt studies should be assigned to IRB 7 or 8 when feeding the submission over to PennERA
- Assignment to PennERA should occur as soon as possible for all Initial submissions to ensure the ancillary review items on the HRPP page are sent out. If the first submission is returned, the PennERA determination for that action should be set to “Issue Identified”. Any subsequent returned submissions that appear in PennERA should also be set to “Issue Identified”
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES
5.2 INITIAL REVIEW – Exempt Research and Limited IRB Review

PENN ERA

Summary Page Data Entry - the following fields should be completed as follows on the summary page for an exemption be sure to check the summary page is correct after the letter has been drafted.

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Record Number</td>
<td>823100</td>
</tr>
<tr>
<td>Created on</td>
<td>31-Jul-2015</td>
</tr>
<tr>
<td>Initial Submission Date</td>
<td></td>
</tr>
<tr>
<td>Research Type</td>
<td>Biomedical</td>
</tr>
<tr>
<td>Risk Level</td>
<td>Minimal</td>
</tr>
<tr>
<td>Review Category</td>
<td>Exempt</td>
</tr>
<tr>
<td>Original Meeting Date</td>
<td>31-Jul-2015</td>
</tr>
<tr>
<td>Board Name</td>
<td>IRB #7</td>
</tr>
<tr>
<td>Determination</td>
<td>Exempted</td>
</tr>
<tr>
<td>Determination Date</td>
<td>31-Jul-2015</td>
</tr>
<tr>
<td>Short Title</td>
<td>IRB QA Protocol for examples</td>
</tr>
<tr>
<td>Full Title</td>
<td>IRB Protocol For Internal Quality Monitoring and Assurance</td>
</tr>
<tr>
<td>Objectives and Purposes</td>
<td>This protocol has been developed for the ORA staff to create training material, troubleshoot real-time problems with the application, and compile necessary information about policies and procedures for response to external audit. This protocol has been developed for the ORA staff to create training material, troubleshoot real-time problems with the application, and compile necessary information about policies and procedures for response to external audit. This protocol has been developed for the...</td>
</tr>
<tr>
<td>Overview</td>
<td>Any helpful notes can go here (note the exempt category or anything else unique about this review that may help IRB staff in the future)</td>
</tr>
</tbody>
</table>

Agenda Notes General Review Page Data Entry – Be sure to fill in:
- Confirmation code
- Submit Date
- Exemption Category
- Description field data entry
- A document list is NOT required for Exemptions. You do not have to identify the HSERA application either since the confirmation code is identified in the first field.

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5.2 INITIAL REVIEW – Exempt Research and Limited IRB Review

- Follow the checklist instructions for UDFS related to HIPAA waivers and Limited IRB review. These boxes must be checked for the letter template to include the appropriate determination language.

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5.2 INITIAL REVIEW – Exempt Research and Limited IRB Review

- IRB Reviewer (Must be an IRB Director)
- Determination (must be Exempted)
- Determination Date (always same as review meeting date)
- Risk Level (Minimal)
- Prior to drafting the letter you must Update the summary. When the Update Summary fields appear you must update ALL the available sections since this is an initial review and the summary page has not been set yet.
- Please draft a letter using the Exemption template.
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES
5.3 INITIAL REVIEW – Prime/Umbrella Grant/Just in Time (JIT) reviews

OVERVIEW
This section defines and describes procedures for reviewing and documenting approval for Prime/Umbrella Grants and “Just in Time” (JIT) applications. The Workflow for Prime Grants and JIT approvals follow the same workflow for expedited assignments described elsewhere in the GDO. If the submission is received via a paper or email submission process, a protocol will be created in PennERA, the documents will be uploaded, and Senior Staff will be notified that the submission is ready for review. This section is limited to definitions, screening, and documentation guidance.

DEFINITIONS
Prime or Umbrella Grants are a single administrative submission that does not include actual research procedures but instead encompasses multiple projects that will conduct research with a common hypothesis, set of investigators or data set. The differences among the active research protocols are minimal. Prime Grants must maintain active IRB approval along with maintaining separate IRB approval for each of the research protocols funded by the Prime Grant.

Just In Time (JIT) Approvals are requested when an investigator has developed a proposal for funding and their grant application requires IRB approval but the time period for requesting the funds does not allow for a full IRB review process to take place. Investigators may submit an abbreviated application through HSERA and request rushed approval of the concept of their study so that they may proceed with their grant application. Research is not permitted under a Just In Time approval. If the funds are obtained and research will commence, the investigator is required first to either make significant revisions to the existing application or submit an entirely new application for the IRB to conduct a complete initial review to allow for research to begin.

SCREENING GUIDANCE
The Screener conducts an initial review examining the HS-ERA application and any submitted study documents to determine if the concept of the project can be approved. Submitters are required to complete the HS-ERA application and upload a copy of the grant application. The screener reviews these documents to determine if this protocol will be able to be conducted in accordance with the federal regulations and institutional policies. Any issues or concerns with the application or study documents (or lack thereof) hindering the approval in concept should be noted within a problems/issues document. This problems/issues document should also include any recommendations, comments on review status, and questions for the study team.

If the screener is unsure if the project would be approved for the enrollment of human subjects, he/she should consult with the Director/designee and/or the IRB chair for the assigned board. If the screener has identified issues with the submission that must be addressed before final review can occur, the issues should either be addressed via email or the submission should be returned. Procedures for returning submissions are described elsewhere in the GDO.

If no issues were noted during the initial review or if the issues raised by the administrator have been resolved, then the application is assigned to the appropriate Board in PennERA and assigned to the final reviewer for approval.

DOCUMENTATION OF THE REVIEW

HSERA
- Comments should be added to HSERA to provide the completed Exempt screening worksheet with reviewer notes and letter drafting instructions
- Comments should be added to HSERA to provide any email correspondence related to the review and any documents related to the review received from the study team outside of HSERA
- Text only comments regarding details of the review may be added at the reviewer’s discretion.
- If the application was received outside of HSERA this documentation should be attached to PennERA.
- Prime and JIT applications should be assigned to IRB 7 or 8 when feeding the submission over to PennERA.
 Assignment to PennERA should occur as soon as possible for all Initial submissions to ensure the ancillary review items on the HRPP page are sent out. If the first submission is returned, the PennERA determination for that action should be set to “Issue Identified”. Any subsequent returned submissions that appear in PennERA should also be set to “Issue Identified”. Only the submission which is placed for final approval should be set to Pending.

**PENN ERA**

Summary Page - be sure to verify that the appropriate fields are filled in as shown below

![Summary Page](image-url)

- **Record Number**: 811698
- **Created on**: 10-May-2010
- **Initial Submission Date**: 06-May-2010
- **Research Type**: 
- **Risk Level**: No risk level determined
- **Reviewers**: None Selected Set
- **Determination Date**: 09-Mar-2018
- **Approved To**: 08-Mar-2018
- **Short Title**: Penn-CMU Roybal Center on Behavioral Economics and Health
- **Full Title**: Penn-CMU Roybal Center on Behavioral Economics and Health
- **Objectives and Purposes**: 1. To determine if, compared to controls, patients receiving peer counseling will have a greater reduction in HbA1c. 2. To determine if, compared to controls, patients receiving financial incentives will have a greater reduction in HbA1c. 1. changes in HbA1c 1. counts of the number of hypoglycemic events (all and serious -- ED and hospitalizations) 2. description of the number of peer encounters by arm
- **Overview**: Project updated to reflect prime grant request for the P30 center grant
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES
5.3 INITIAL REVIEW – Prime/Umbrella Grant/Just in Time (JIT) reviews

Agenda Notes General Review Page Data Entry – Be sure to fill in:
- Confirmation code
- Submit Date
- Accurate Review type (Initial Review)
- Description field data entry
- A document list may be required for Prime or JIT. Please follow screener instructions.

<table>
<thead>
<tr>
<th>General</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Submission Number</strong></td>
</tr>
<tr>
<td><strong>Submit Date</strong></td>
</tr>
<tr>
<td><strong>Coordinator</strong></td>
</tr>
<tr>
<td><strong>Review Type</strong></td>
</tr>
<tr>
<td><strong>Exemption Categories</strong></td>
</tr>
<tr>
<td><strong>Expedited Categories</strong></td>
</tr>
<tr>
<td><strong>Review Activities</strong></td>
</tr>
<tr>
<td><strong>Created On</strong></td>
</tr>
</tbody>
</table>
| **Description**             | Electronic Submission
H3 ERA Confirmation #ddhdei

This is a pilot study being conducted at the Philadelphia VA Medical Center (PVAMC). It is part of a P30 center grant awarded to the University of Pennsylvania. We are submitting this pilot study as the prime grant. We will submit all P30 pilot projects to the Penn IRB in the future prior to the start of the pilot project. The P30 is a 5-year award that will fund 1-3 year-long pilot studies per year.

Documents included with the application noted below are approved:
-H3 ERA Initial Review Submission (Confirmation #ddhdei), Dated 5/6/10
5.3 INITIAL REVIEW – Prime/Umbrella Grant/Just in Time (JIT) reviews

Letter Drafting Review Details Page Data Entry - Be sure to fill in and VERIFY:
- Correct Review Category (always Administrative)
- Board Name (always IRB 7 or 8)
- Agenda Radial (YES)
- Agenda Date (Next available – Never in the past)
- Review meeting date (Always same as determination date)
- IRB Reviewer (Must be an IRB Director)
- Determination (must be Approved Concept in Principle)
- Determination Date (always same as review meeting date)
- Risk Level (No Risk Level Determined)
- Date From (same as determination date)
- Date To (these types of approvals expire after 12 months so this must be accurate and appear in the letter)
- Prior to drafting the letter you must Update the summary. When the Update Summary fields appear you must update ALL the available sections since this is an initial review and the summary page has not been set yet.
- Please draft a letter using the PRIME template.
OVERVIEW
New human subject’s research protocols that meet the Minimal Risk criteria for Expedited categories 1-7 are screened by experienced IRB analysts at the administrator or senior administrator level. The workflow for Initial Expedited submissions follows the workflow described elsewhere in the GDO for HSERA assignments. This section describes procedures and guidance for screening and documenting the review.

PROCEDURES
After receipt of the assignment, the Screener conducts the initial screening by examining the HS-ERA application and any submitted study documents to determine:
1. If the protocol meets the criteria for Expedited approval.
2. The appropriate categories for approval (1-7)

During the screening process, the screener reviews and completes each required field of the IRB Initial Expedited Checklist to ensure complete and consistent review of the expedited review regulations and institutional requirements and to document the review. Please refer to the Initial Expedited Checklist for complete details and information regarding criteria for approval of an Expedited protocol.

Any issues or concerns with the application or study documents (or lack thereof) affecting the criteria for approval should be noted within the checklist. Upon completion of the screening, the issues identified should either be addressed by the study team via email or the submission should be returned for corrections. Procedures for returning submissions are described in a separate section of the GDO.

If the screener determines that the study does not qualify for expedited review they should either:
1. Conduct an Exempt screening and recommend approval for Exemption
   – OR--
2. Return the submission to the study team to provide any additional information needed for the convened review. The Re-submission should then be screened and prepared for Convened review.

GUIDANCE
Regulations dictate that Minimal Risk research which is not FDA regulated should not require annual continuing review. If the screener determines that a minimal risk study should be required to submit annual or more frequent renewal, the rationale should be discussed with IRB directors and should be well documented.

DOCUMENTATION OF THE REVIEW
HSERA
- Comments should be added to HSERA to provide the completed Expedited screening worksheet with reviewer notes and letter drafting instructions.
- Comments should be added to HSERA to provide any email correspondence related to the review and any documents related to the review received from the study team outside of HSERA.
- Text only comments regarding details of the review may be added at the reviewer’s discretion.
- All Expedited studies should be assigned to IRB 7 or 8 when feeding the submission over to PennERA (Biomedical to IRB 7 and Social/Behavioral/Educational to IRB 8)
- Assignment to PennERA should occur as soon as possible for all Initial submissions to ensure the ancillary review items on the HRPP page are sent out. If the first submission is returned, the PennERA determination for that action should be set to “Issue Identified”. Any subsequent returned submissions that appear in PennERA should also be set to “Issue Identified”. Only the submission which is assigned for final approval should reflect a “Pending status”
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES

5.4 INITIAL REVIEW – Expedited Reviews

**PENN ERA**

**Summary Page** - be sure to verify that the appropriate fields are filled in as shown below. Please note that if the determination should be standard Approval, the study should be given an expiration date. Please closely follow the screener instructions for approval determinations and expirations.

![Summary Page Screenshot](image)

**Agenda Notes General Review Page Data Entry** – Be sure to fill in:
- Confirmation code
- Submit Date
- Accurate Review type (Initial Review)
- Expedited Categories
- Description field data entry
- A complete document list may be required. Please follow screener instructions.
Letter Drafting Review Details Page Data Entry: Be sure to fill in and VERIFY:

- Correct Review Category (always Expedited)
- Board Name (always IRB 7 or 8)
- Agenda Radial (YES)
- Agenda Date (Next available –Never in the past)
- Review meeting date (Always same as determination date)
- IRB Reviewer (Must be an IRB Director)
- Determination (Should be Approved (NoCR) unless otherwise stated in screening checklist)
- Determination Date (always same as review meeting date)
- Risk Level (Minimal)
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES

5.4 INITIAL REVIEW – Expedited Reviews

- **Date From** (same as determination date)
- **Date To** (should be blank to align with No CR. Please refer to screener instructions regarding expiration)
- Prior to drafting the letter you must Update the summary. When the Update Summary fields appear you must update ALL the available sections since this is an initial review and the summary page has not been set yet.
- Please draft a letter using the Expedited Initial Approval template.
OVERVIEW
This section provides information regarding Expanded Access Protocols to supplement the information provided in IRB SOP SC 502 including:
- Types of various expanded access types
- Guidance for screening and documenting review

The criteria for investigators to properly submit an expanded access request to FDA and IRB are clearly delineated in the guidance document provided here: https://irb.upenn.edu/how-submit-penn-irb/expanded-access

TYPES OF EXPANDED ACCESS AND LEVEL OF IRB REVIEW
While some Expanded Access Protocols require Convened Review, the complete information is provided in this section for improved staff comprehension and convenience. Level of review required is explicitly stated for each.

<table>
<thead>
<tr>
<th>Type of Expanded Access</th>
<th>Product</th>
<th>Level of Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Patient Emergency Use</td>
<td>Drug</td>
<td>Administrative Review post hoc</td>
</tr>
<tr>
<td></td>
<td>Device</td>
<td>• Administrative Review post hoc; or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Physician Chair review if concurrence is requested prior to administration</td>
</tr>
<tr>
<td>Single Patient Compassionate Use</td>
<td>Drug / Device</td>
<td>• Convened Review; or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Physician Chair review when there is documented notification of expedited review to the FDA by the submitter (e.g., in the cover letter to FDA and/or box 10b is checked on FDA form 3926).</td>
</tr>
<tr>
<td>Intermediate-Size Population Compassionate Use</td>
<td>Drug only</td>
<td>Convened Review or Physician Chair review**</td>
</tr>
<tr>
<td>Treatment Use</td>
<td>Drug / Device</td>
<td>Convened Review</td>
</tr>
<tr>
<td>Humanitarian Use</td>
<td>Device only</td>
<td>Convened Review</td>
</tr>
</tbody>
</table>

**The IRB staff will consider whether there is adequate time and resources to allow for the protocol to be scheduled and reviewed by the appropriate convened IRB without negatively affecting potential benefit to patients. The Director and/or physician IRB Chair will be consulted as needed.

The following applications may be eligible for expedited review*:
- The treatment/compassionate use is time sensitive
- The treatment/compassionate use is in the best interest of the patient and/or the prospect of direct benefit exists
- The risk/benefit ratio for the proposed treatment/compassionate use request is favorable

GUIDANCE FOR SCREENING AND DOCUMENTING SINGLE PATIENT EMERGENCY USE

Receipt
- Emergency Use submissions are received by the IRB via email
- Emergency Use submissions do not require HSER application but may be received through HSER.

Review The screener should confirm the following:
- The consent form should reflect that the product is an investigational treatment. The consent form should not mention research. Data may be used for research, but the treatment cannot be presented as research. Research HIPAA authorization is not required unless data may be used for research.


UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES

5.5 INITIAL REVIEW – Expanded Access Protocols (Single Patient, Emergency use, Compassionate Use, Humanitarian Use)

- The Expanded Access Application Form has been submitted, along with the required documents outlined on page 1 of the form. All necessary information in the form has been completed appropriately.
- Any questions or requests missing documentation should be sent to the submitter.

Post Review Actions:
- All documents received should be compiled and attached to a new record created in PennERA
- The Data entry on the summary page should indicate Administrative review Category and an Acknowledgement determination. Submission and determination Dates should be complete. All fields for titles, descriptions and overview should reflect Emergency Use. The IND/IDE holder and IND/IDE number fields should be filled in.
- The Drugs or Devices section of PennERA should be completed with the available information
- The Action data entry on the first review page should indicate “Email” submission number, Submit date, and a description to indicate emergency use including a list of submitted documents. On the second review page, data entry should reflect Administrative review category, Board #, Agenda Assignment, Agenda date, review date, Determination of Acknowledged, Determination date. The reviewer should be assigned as a Director, Chair, or Senior Administrator (whoever screened the submission)
- A letter does not need to be drafted unless the submitter has requested one or the submission came through HSERA. If a letter has been requested, please draft a letter using the HS Emergency Use letter template. The letter should include a complete document list. If a letter has not been requested, the screener should confirm receipt of the submission via email.

GUIDANCE FOR SINGLE PATIENT COMPASSIONATE USE

Compassionate Use submissions must be approved by the FDA and IRB BEFORE the patient is treated.

Receipt
- Single Patient Compassionate Use submissions are received by the IRB via email
- Single Patient Compassionate Use submissions do not require HSERA application but may be received through HSERA.

Screening Process
The screener should confirm the following:
- The consent form should reflect that the product is an investigational treatment. The consent form should not mention research. Data may be used for research, but the treatment cannot be presented as research. Research HIPAA authorization is not required unless data may be used for research.
- The consent form should accurately reflect the IND/IDE sponsor and should identify the product manufacturer.
- The Expanded Access Application Form has been submitted, along with the required documents outlined on page 1 of the form.
- All necessary information in the form has been completed appropriately.
- If expedited review is requested, the appropriate documentation notifying FDA has been provided by the study team.
- Any questions or requests missing documentation should be sent to the submitter.

Post Screening Actions:
- Based on the documentation provided, Convened Review or Expedited Chair review should be scheduled.
- If the submission is received via email, the documents should be compiled in an organized fashion. These documents should be provided to the Board or Chair depending on the level of review.
- If the submission is received via email, the compiled documents should be attached to a new record created in PennERA
- Data Entry in PennERA should align with basic requirements for Full board actions including expiration date.
  - Requests requiring convened review should have data entry that aligns with other full board actions
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES

5.5 INITIAL REVIEW – Expanded Access Protocols (Single Patient, Emergency use, Compassionate Use, Humanitarian Use)

- Requests receiving IRB Chair expedited review should also have data entry that aligns with full board actions.
  - Please draft a letter using the HS Treatment Use IND template.
    - If the request is for a Device, the letter should be revised to indicate IDE in any areas where IND is stated.
    - For both drugs and devices, the IND or IDE number should be inserted into the letter.

The IRB does not require detailed continuing review submissions (i.e. progress report, monitoring summary, etc.) for annual renewals of single patient compassionate use treatments unless treatment is ongoing at the time of IRB approval expiration.

GUIDANCE FOR INTERMEDIATE-SIZE POPULATION IND PROTOCOL

Intermediate-Sized Population IND/IDE protocols are for the treatment of multiple or many patients who may benefit from the expanded access of a drug or device that is not approved for their condition. These protocols are often developed when the FDA has received a significant number of single patient requests for the investigational article. The number of patients treated must be less than typically included in a widespread access/treatment IND protocol to qualify. Any IRB administrator assigned to screen this type of submission should be aware of the following:

- These are not considered research so cannot be quantified as a pilot or clinical trial
- Intermediate-Sized Population IND/IDE protocols require convened IRB review
- These must be approved by the FDA and IRB before patients are treated
- These require an HSERA submission
- Screening and documentation of these applications should align with IRB procedures for any other greater than minimal risk biomedical study that requires convened review.

GUIDANCE FOR WIDESPREAD ACCESS/TREATMENT IND PROTOCOL

These protocols are quite rare due to the very specific criteria outlined by the FDA. Those criteria are outlined here: https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/ucm431769.htm. Any IRB administrator assigned to screen this type of submission should be aware of the following:

- There are various types of Treatment IND protocols (Group C Treatment IND, Parallel Track)
- Widespread Treatment IND/IDE protocols require convened IRB review
- These must be approved by the FDA and IRB before patients are treated
- These require an HSERA submission
- Screening and documentation of these applications should align with IRB procedures for any other greater than minimal risk biomedical study that requires convened review.

GUIDANCE FOR HUMANITARIAN USE DEVICE (HUD)

Humanitarian Use Device protocols are not considered expanded access by FDA definition. Their purpose is to provide access to investigational devices for patients who suffer from Orphan Diseases (diseases or conditions which affect or manifest in not more than 8,000 individuals in the United States per year). Any IRB administrator assigned to screen this type of submission should be aware of the following:

- HUD protocols require convened IRB review
- HUD Protocols require convened annual continuing review but the submission may not contain the same level of detail as a clinical trial.
- These must be approved by the FDA and IRB before patients are treated
- These require an HSERA submission
- Screening and documentation of these applications should align with IRB procedures for any other greater than minimal risk biomedical study that requires convened review.
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES

5.6 Continuing Reviews Eligible for Expedited Review

OVERVIEW
This section outlines procedures and guidance for conducting and documenting expedited continuing reviews. Continuing reviews are received via HSERA and paper to request the renewal of ongoing research. The workflow for all Expedited Continuing Reviews follows the workflow outlined in section 4.1 of the GDO.

PROCEDURES
Upon receipt of a continuing review submission assignment (both paper and HSERA) the screener utilizes the appropriate Continuing Review Checklist to assess completeness and appropriateness of the renewal request. Every screening should begin with the most recent version of the blank template. Template copies of these checklists are available on the shared G drive:

- **Greater Than Minimal Risk CR Checklist**: If the study was initially assessed as Greater than Minimal risk but now qualifies for Cat 8 expedited review
- **Minimal Risk CR Checklist**: If the study was initially assessed as Minimal risk but was determined to require annual renewal.
- In some cases Expedited continuing review screenings conducted by senior or director level staff may be documented via text notes only without utilizing a continuing review worksheet.

Each of these checklists includes specific areas of assessment for the application and submitted documents. The IRB screener should determine the appropriate expedited review category and that the criteria for re-approval are met. Requirements for continuing review submissions are outlined within the submission form that must be completed by the submitting study team. The requirements for approval of a continuing review are outlined in the checklist. The checklist should be completed with adequate notes to assist the final reviewer in determining whether approval may be granted.

If the IRB screener determines the submission is incomplete or not yet ready to be reviewed, the submission is returned to the submitter for revision without approval. If minor issues are identified, they may be addressed with the study team via email when appropriate. Paper submissions cannot be returned. The IRB screener should work with the study team via email to rectify any issues with the submission.

If no issues were noted during the review or if the issues raised by the IRB screener have been resolved, the review should be appropriately documented and the submission should be assigned to an IRB Director or IRB Chair for final review.

The final reviewer reviews the application to determine if the criteria for expedited re-approval have been met. If any questions or concerns related to the criteria for re-approval are identified, the approver communicates these issues to the IRB Administrator/IRB Staff. At this time, the submission may be returned for revisions or issues may be addressed via email.

Any minor or administrative issues identified that are not resolved during screening or final review may be communicated via notes in the letter to the study team informing them of required / requested corrective action.

If at any point in the above processes, the screener or reviewer determines that the study requires convened IRB review, a Senior IRB Administrator is notified. The IRB screener should share their notes and comments about the submission with appropriate IRB staff and inform the study team.
5.6 Continuing Reviews Eligible for Expedited Review

GUIDANCE

- While screening a continuing review it is advised to check the initial review approval for any notes regarding waivers or other important determinations that would affect future reviews.

- While screening a continuing review it is advised to check continuing review documentation from previous years (if available) to confirm the appropriate expedited categories and ensure consistent review each year.

- Screening of continuing reviews requires confirmation of active CITI training for all study staff.
  - If training is expired or not properly documented for the Principal Investigator, the research should be conditionally re-approved with a stipulation that updated documentation of training be submitted via formal response unless the study is determined to not require continuing review going forward.
  - If training is expired or not properly documented for any other member of the study team, a note should be included in the determination letter requiring renewal of training for each person prior to continuing engagement in research. The note should be clear that anyone with expired or undocumented training is not permitted to engage in any human subject’s research.
  - Template Notes for these issues are available in the Letter Language Templates document stored on the Gdrive.

- During the screening of a continuing review the summary page of Penn ERA should be reviewed in its entirety to ensure all appropriate fields are completed. Any missing or conflicting information should be corrected prior to assigning for final review. A screener may need to request assistance from a senior staff member to determine any necessary changes to information on the summary page.

- During the assessment of the summary page, any open ended notes should be reviewed with a senior staff member to determine whether the pending item has been completed, whether the note should be revised or removed.

- Assessment of Continuing Review submissions includes determining whether continuing review will still be required based on the status of the study and the Expedited Review regulations. Documentation of studies that do not require continuing review is slightly different than those that do.
  - **When Continuing Review is required**: Determination is “Approved”, An Approved To (expiration) date must be included, qualifies for Conditional re-approval
  - **When NO CR**: Determination is “Approved (No CR)”, an Approved To (expiration) date should not be included, does not qualify for Conditional re-approval

- FDA regulated studies (research with drugs or devices) must continue to submit continuing review until the study is closed even if they meet the other status and expedited criteria for No CR.

DOCUMENTATION OF THE REVIEW

HSERA

- Comments should be added to HSERA to provide the completed screening worksheet with notes and letter drafting instructions, any email correspondence related to the review and any documents related to the review received from the study team outside of HSERA
- Text only comments regarding details of the review may be added at the FINAL reviewer’s discretion.
- Expedited Continuing Reviews should be assigned to whatever Board is identified on the summary page in PennERA
If any submissions assigned to PennERA are returned, the PennERA determination for that action should be set to “Issue Identified”. Any subsequent returned submissions that appear in PennERA should also be set to “Issue Identified”. Only the submission which is assigned for final approval should reflect a “Pending” status.

**PAPER**
- Upon completion of the screening, the completed worksheet and any email correspondence with the study team should be printed and attached to the study file along with the full packet of submitted paper documents.
- The study file and documents should be placed together on the signing desk for IRB Director final review

**PENN ERA – Documentation in PennERA for HSERA and Paper Continuing Reviews is the same**

**Summary Page** - be sure to verify that the appropriate fields are filled in as shown below. Please note that if the determination should be standard Approval, the study should be given an expiration date. Please closely follow the screener instructions for approval determinations and expirations.
**Agenda Notes General Review Page Data Entry – Be sure to fill in:**

- Confirmation code (for HSERA submissions place the HSERA confirmation code. For paper place the Submit date)
- Submit Date
- Accurate Review type (Review – Request for Continuation)
- Expedited Categories
- For paper submissions the review activities should be completed for each step of the assignment workflow
- Description field data entry should identify whether the submission is paper or electronic and include the study Purpose
- A complete document list may be required. Please follow screener instructions. The HSERA application should always be listed even if a complete document list is not required

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Be sure to check the appropriate UDFs for Expedited Determinations according to the screening checklist to ensure the correct template language appears in the letter
Letter Drafting Review Details Page Data Entry - Be sure to fill in and VERIFY:
- Correct Review Category (always expedited)
- Board Name
- Agenda Radial (YES)
- Agenda Date (Next available –Never in the past)
- Review meeting date (Always same as determination date)
- IRB Reviewer (Must be an IRB Director or Chair)
- Determination (should be either Approved No CR, Approved, or Conditional Re-approval. Please refer to screener checklist)
- Determination Date (always same as review meeting date)
- Date From (same as determination date)
- Date To (should be blank to align with No CR. Please refer to screener instructions regarding expiration)
- Prior to drafting the letter you must update the summary. When the Update Summary fields appear you must update the Determination, Determination Date, Approved From, and possibly approved to (if there is an expiration date)
- The same document list from the agenda page should be entered into the Comments field on this page.
- Please follow screener instructions for notes in the Comments and Provisions fields
- Please draft a letter using the Expedited CR Approval template.
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES
5.7 Modifications Eligible for Expedited Review

OVERVIEW
This section outlines procedures and guidance for conducting and documenting expedited modifications reviews. Modifications are received via HSERA and paper to request amendments or report updates to ongoing research. Modifications may be made for research that is Exempt, Minimal risk, or Greater Than Minimal risk. The workflow for all Expedited modifications follows the workflow outlined in section 4.1 of the GDO.

PROCEDURES
Upon receipt of a modification submission assignment (both paper and HSERA) the screener utilizes the appropriate Modification Checklist to assess completeness and appropriateness of the request. Every screening should begin with the most recent version of the blank template. Template copies of these checklists are available on the shared G drive for screening modifications:

- **Modification Standard screening checklist** – To be used for any expedited modification submitted for Exempt, Minimal risk, or Greater Than Minimal risk research
- **Relying IRB Modification checklist** - To be used for any expedited modification for research where Penn is relying on an external IRB (Reliance Agreements are discussed in detail in separate GDO sections)
- **Site Addition Modification Checklist** – To be used when Penn serves as the IRB of record for other sites and the modification seeks to add a new site (Penn as the Central IRB is discussed in detail in separate GDO sections)
- **Response to Stipulations Checklist** – To be used when the purpose of the modification is to respond to IRB stipulations (response stipulations are discussed in detail in separate GDO sections)
- In some cases Expedited modification screenings that are limited to minor administrative changes or modifications conducted by senior or director level staff may be documented via text notes only without utilizing the checklists.

Each of these checklists includes specific areas of assessment for the application and submitted documents. Upon review of the application and submitted documents the screener should first confirm whether the modification qualifies for expedited review. The screener should assess each change outlined in the summary of changes and determine:

- whether the changes are acceptable in context of criteria for approval
- whether the changes are appropriately documented in the application, protocol, consent form and other applicable documents
- whether the rationale provided for each change is provided and appropriate

Requirements for modification submissions are outlined within the submission form that must be completed by the submitting study team. The checklist should be completed with adequate notes to assist the final reviewer in determining whether approval may be granted.

If the IRB screener determines the submission is incomplete or not yet ready to be reviewed, the submission is returned to the submitter for revision without approval. If minor issues are identified, they may be addressed with the study team via email when appropriate. Paper submissions cannot be returned. The IRB screener should work with the study team via email to rectify any issues with the submission. Procedures for returning submissions are outlined elsewhere in the GDO.

If no issues were noted during the review or if the issues raised by the IRB screener have been resolved, the review should be appropriately documented and the submission should be assigned to an IRB Director or IRB Chair for final review.
The final reviewer reviews the application to determine if the criteria for expedited re-approval have been met. If any questions or concerns related to the criteria for re-approval are identified, the approver communicates these issues to the IRB Screener. At this time, the submission may be returned for revisions or issues may be addressed via email.

Any minor or administrative issues identified that are not resolved during screening or final review may be communicated via notes in the letter to the study team informing them of required / requested corrective action.

If at any point in the above processes, the screener or reviewer determines that the study requires convened IRB review, a Senior IRB Administrator is notified. The IRB screener should share their notes and comments about the submission with appropriate IRB staff and inform the study team.

GUIDANCE
- Expedited Modifications may include changes which alter the risk profile of the study. All modifications should be scrutinized to determine whether a reassessment of the review level is required. For example:
  - Do the changes to an Exempt study require assignment of expedited categories or increase the risk to require convened review?
  - Do the changes to an Expedited protocol require convened review?
  - Do the changes to an Expedited protocol require additional review categories not previously applied?
  - Modifications which result in changes to the review level or review categories should be discussed with senior level staff prior to placing for final review.

- Expedited Modifications require submission of a summary of changes. The summary of changes should include a full list of all changes being made and the rationale for those changes. If this information is not included or is incomplete, the submission should be returned or the information should be requested via email.

- Expedited Modifications may be Approved or Acknowledged. The data entry in pennERA and in the determination letter should appropriately reflect the determination from the final reviewer.

DOCUMENTATION OF THE REVIEW (STANDARD EXPEDITED MODIFICATIONS ONLY)

HSERA
- Comments should be added to HSERA to provide the completed screening worksheet with notes and letter drafting instructions.
- Comments should be added to HSERA to provide any email correspondence related to the review and any documents related to the review received from the study team outside of HSERA
- Text only comments regarding details of the review may be added at the FINAL reviewer’s discretion.
- Modifications should be assigned to whichever board the protocol is assigned to on the summary page of PennERA
- If any submissions assigned to PennERA are returned, the PennERA determination for that action should be set to “Issue Identified”. Any subsequent returned submissions that appear in PennERA should also be set to “Issue Identified”. Only the submission which is assigned for final approval should reflect a “Pending” status.

PAPER
- Upon completion of the screening, the completed worksheet and any email correspondence with the study team should be printed and attached to the study file along with the full packet of submitted paper documents.
- The study file and documents should be placed together on the signing desk for IRB Director final review

PENN ERA – Documentation in PennERA for HSERA and Paper Modifications is the same
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES
5.7 Modifications Eligible for Expedited Review

Summary Page: Modifications may result in changes to some study specific information documented on the summary page of PennERA (title, staff, PI, IND information, Reliance agreement information). It is the responsibility of the screener to either make the updates or clearly communicate what changes should be made to the letter drafter. Typically modifications DO NOT result in changes to any of the dates captured on the summary page. Close attention should be paid to approval and expiration dates on the summary page at the time of approval of modifications. Since modifications may be received for any type of research, a screenshot is not provided.

Agenda Notes General Review Page Data Entry – Be sure to fill in:
- Confirmation code (for HSERA submissions place the HSERA confirmation code. For paper place the Submit date)
- Submit Date
- Accurate Review type (Amend – Amendment or Modification)
- For paper submissions the review activities should be completed for each step of the assignment workflow
- Description field data entry should identify whether the submission is paper or electronic and include a modification
- Summary. The summary should be based on what the study team submits to explain the purpose of the submission.
- A complete document list may be required. Please follow screener instructions. The HSERA application should always Be listed even if a complete document list is not required

Be sure to check the appropriate UDFs for Expedited Determinations according to the screening checklist to ensure the correct template language appears in the letter
Letter Drafting Review Page Data Entry - Be sure to fill in and VERIFY:
- Correct Review Category (May be Expedited, Exempt, or Administrative)
- Board Name
- Agenda Radial (YES)
- Agenda Date (Next available – Never in the past)
- Review meeting date (Always same as determination date)
- IRB Reviewer (Must be an IRB Director or Chair)
- Determination (refer to determination logged by final reviewer)
- Determination Date (always same as review meeting date)
- Risk Level
- Date From (should be blank for most mods unless you are instructed to change the approval period of the study)
- Date To (should be blank for most mods unless you are instructed to change the approval period of the study)
- If there are no personnel changes included with the modification, the summary should not be updated.
  Modifications typically DO NOT require changes to the determination or dates on the summary. Please consult with the screener prior to making any summary changes.
- Please draft a letter using either the Amendment Expedited template OR Amendment Acknowledgement template depending on the determination.
OVERVIEW
This section outlines procedures and guidance for conducting and documenting Deviation reviews. Deviation submissions are received via HSERA and paper. The workflow for Deviations follows the workflow outlined in section 4.1 of the GDO.

Deviations that are found to require convened review require a complete expedited review procedure for acknowledgement of receipt with a determination letter issued to the study team. The additional convened review will take place separately but utilize the same submission. This section only describes those expedited review procedures and the procedures for creating the separate review for the Convened Agenda. Convened Deviation review procedures are described elsewhere in the GDO.

PROCEDURES
Upon receipt of a Deviation submission assignment (both paper and HSERA) the screener utilizes the Reportable Event and Deviation Checklist to conduct the screening. Every screening should begin with the most recent version of the blank template. Template copy of the checklist is available on the shared G drive.

By reviewing the contents of the HSERA or Paper Deviation submission form and supplemental documents the screener should determine whether all necessary documentation has been provided to evaluate the deviation report. The study team should be contacted via email to provide additional information if the contents of the submission are insufficient. Due to the timeliness requirements for reporting deviations, deviation submissions should not be returned during expedited screening unless absolutely necessary. Please discuss with a Senior Administrator or director before returning. Procedures for returning HSERA submissions are outlined elsewhere in the GDO. Paper submissions cannot be returned.

The screener should fill in all areas of the checklist and determine whether the Deviation would require convened review for assessment of serious or continuing noncompliance. Definitions of noncompliance and the criteria for making these assessments are outlined in the checklist. Upon completion of the screening one of the following actions may be taken by the screener:

1. The screener should consult an IRB Director or IRB Chair via email regarding additional information that is needed from the study team. Based on consultant recommendations, the study team should be contacted for additional information. New Information should be shared with the consultant until there is enough evidence that a determination can be made. The checklist should be updated to reflect any new information prior to placing for acknowledgement in PennERA.

2. The screener may determine that the deviation should be acknowledged with no further action required and place for final review in PennERA by an IRB Director or Chair with this recommendation.

The Final Reviewer finds the submission in HS-ERA or reviews the paper documents. The reviewer reviews the application to determine if the criteria for expedited acknowledgement have been met. If any questions or concerns related to the criteria for acknowledgement are identified, the final reviewer communicates these issues to the IRB Screener to either be addressed by the study team prior to logging an expedited decision OR prior to the convened meeting date if convened review is found to be required. If no concerns are raised or the issues raised by the reviewer are appropriately addressed, the reviewer then acknowledges the submission.

Please also note the following regarding procedures for review of deviations:

- All deviations (regardless of level of review required) must be Acknowledged by an IRB Director or IRB Chair
- All deviations (regardless of level of review required) must have a determination letter sent to the study team to acknowledge receipt.
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES

5.8 Deviation Submissions

- Deviations that are found to require convened review should include a specific note to the study team in the acknowledgement letter informing them that convened review is required and if possible, the date of the convened review.

- If at any point in the above processes, it is determined that the deviation(s) requires convened IRB review, the appropriate IRB staff member is notified that they should schedule the submission for convened IRB review. If the Staff member processing the deviation is not the Administrator for the Board in which the deviation is being scheduled, the IRB screener should share their notes and comments about the submission with appropriate IRB Administrator by attaching them to the HSERA comments or providing emailed documents for paper review.

GUIDANCE

- Assessment of Deviations requires sufficient detail provided by the study team to:
  - evaluate the deviation report
  - consider the study team’s corrective action plan
  - justify whether changes to the study documents will or will not be made

- Changes to study documents as a result of a deviation must be submitted as a modification.

- It is permissible for a study team to submit a combined submission via HSERA to seek approval for modifications at the time of reporting a deviation. These submissions would require a modification form and all documents related to modification approval as well as a deviation form and all documents related to deviation acknowledgement. For electronic studies, combined submissions should be received as a Modification since the Deviation submission does not allow for application revisions. Combined submissions for paper studies only require printed copies of the above noted forms and documents.

DOCUMENTATION OF THE REVIEW

HSERA

- Comments should be added to HSERA to provide the completed screening worksheet with notes and letter drafting instructions.

- Comments should be added to HSERA to provide any email correspondence related to the review and any documents related to the review received from the study team outside of HSERA

- Text only comments regarding details of the review may be added at the FINAL reviewer’s discretion.

- Deviation acknowledgements should be assigned to whatever Board is currently documented on the summary page of PennERA

- If any submissions assigned to PennERA are returned, the PennERA determination for that action should be set to “Issue Identified”. Any subsequent returned submissions that appear in PennERA should also be set to “Issue Identified”. Only the submission which is assigned for final approval should reflect a “Pending” status.

PAPER

- Upon completion of the screening, the completed worksheet and any email correspondence with the study team should be printed and attached to the study file along with the full packet of submitted paper documents.

- The study file and documents should be placed together on the signing desk for IRB Director final review or emailed to the IRB Chair reviewer.

PENN ERA

Summary Page- Deviations generally do not require changes to the summary page at all. Letter drafters should consult with screeners prior to making any updates.
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES
5.8 Deviation Submissions

Agenda Notes Review Page Data Entry – Be sure to fill in:
- Confirmation code (for HSERA submissions place the HSERA confirmation code. For paper place the Submit date)
- Submit Date
- Accurate Review type (Review – Deviation)
- For paper submissions the review activities should be completed for each step of the assignment workflow
- Description field data entry should identify whether the submission is paper or electronic and include a complete description of the deviation
- A complete document list is required unless otherwise specified by the screener.

**For deviations that are referred for convened review, a secondary review must be created by clicking the blue Add button on the Grey Reviews ribbon. The Board should be assigned as whichever board will conduct the review. This will create a separate letter drafting review page for the convened action. The same agenda notes review page will be used for both the expedited acknowledgement and the convened review. The screen shot below demonstrates that the Full Board review has the radial button selected so that it becomes the final review once the expedited acknowledgement letter has been drafted and sent to the study team. Additional revisions to the Agenda notes page will likely be required to prepare for the convened agenda. Please see the Convened Deviations GDO for more details.
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES

5.8 Deviation Submissions

Letter Drafting Review Page Data Entry (For Expedited Acknowledgement only)- Be sure to fill in and VERIFY:
- Correct Review Category (always expedited)
- Board Name
- Agenda Radical (YES)
- Agenda Date (Next available –Never in the past)
- Review meeting date (Always same as determination date)
- IRB Reviewer (Must be an IRB Director or Chair)
- Determination (always acknowledged)
- Determination Date (always same as review meeting date)
- Please draft a letter using the Amendment Acknowledgement template.
- If the deviation is being scheduled for convened review a note should be placed in the letter to inform the study team such as “Receipt of this deviation has been acknowledged. It has been referred for convened review by IRB # on DATE for non-compliance assessment.”
OVERVIEW
This section outlines procedures and guidance for conducting and documenting expedited Exception Requests including requests for use of Short Form Consents that qualify for Expedited review. Expedited Exception requests are received via HSERA, paper, or Email to request prospective IRB approval for a single process, procedure, or enrollment that departs from the currently approved research protocol. The workflow for Expedited Exception Requests received via HSERA and paper follows the workflow outlined in section 4.1 of the GDO.

The IRB also allows email exception requests for situations where timing or other special circumstances do not allow for the study team to easily access or submit the request through HS-ERA or via the standard paper submission process. The IRB allows for approval of email exceptions however, the study team is advised of the requirement to follow-up with an official submission for completion of the electronic file record in HS-ERA, where applicable. Email exception requests must be emailed to an IRB Director.

PROCEDURES

HSERA & Paper Submissions
Upon receipt of an Expedited Exception Request assignment (both paper and HSERA) the screener assesses the submission for completeness. A complete Exception request will include:

- The completed Exception Request Submission Form
- Documented approval from the study sponsor, medical monitor and other oversight entities as applicable
- A description of the exception including references to the current protocol, proposed date, rationale, clarification as to why the action is one time, and any plans for communicating the exception to subject
- Assessment of increased risk involved in the exception
- Assessment of subject benefit from the exception
- Assessment of impact of the exception on data integrity
- Declaration of time sensitivity and applicable rationale
- If the HSERA submission is a follow up to a previous IRB Email approval, the IRB email correspondence should be included

The screener should utilize the HSERA application, study file, submitted documents and PennERA to verify:

- the submission is eligible for expedited review
- that there is sufficient rationale to justify the exception request
- whether other monitoring entities have oversight of the protocol and if so request documentation of their approval if appropriate
- A consult review from the Director, Associate Director or Chair may be necessary to determine what questions should be raised to the study team if additional information is needed

The Screener may utilize the Standard Modification screening checklist to document the review or may create their own document to capture the details of the review.
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES
5.9 Exception Requests & Short Form Consent Process

If the Screener determines the submission is incomplete or not yet ready to be reviewed, the submission may be returned to the submitter for revision if time permits, or additional information may be requested via Email. Paper submissions cannot be returned.

If no issues were noted during the review or if the issues raised by the screener have been resolved, the screener assigns the review action to an IRB Director of Board Chair for final review. If issues are raised by the reviewer, the screener relays those issues to the study team and may return the submission in HS-ERA if appropriate.

If at any point in the above processes, the screener or reviewer determines that the Exception requires convened IRB review, a Senior IRB Administrator is notified. The IRB Screener should share their notes and comments about the submission with appropriate IRB staff prior to the convened review and inform the study team.

EMAIL Submissions
Time sensitive exception requests are received by an IRB Director via email and must include all the required documentation for a formal exception request. The IRB Director assesses whether the criteria for expedited approval have been met and whether a timely review is required when determining which staff member should screen. If the action is considered eligible for expedited review, the IRB Director forwards to the appropriate IRB Administrator for screening. The IRB Director forwards the email which includes the exception request to the IRB Administrator and informs the IRB Administrator of the time sensitive nature of the exception request.

The screener then conducts the same processes applied for HSERA and Paper submissions described above. Once the screening is complete and any issues have been addressed, the Exception request documents and screening notes are then emailed to a Director or IRB Chair to request final review and emailed documentation of approval. Once final approval is granted via email one of the following processes may take place:

1. The documentation is forwarded to another IRB staff member to manually create an action in PennERA to generate a rush approval letter.
2. The Study team is informed via email that the exception is approved and an IRB determination letter is not generated until the follow up submission is received in HSERA.

GUIDANCE

Multiple Exceptions for the Same Study
If a single research study submits a significant number of exception requests of a similar nature, the IRB may require a Modification to revise the protocol to eliminate the need for repeat exceptions. IRB Directors should be consulted prior to communicating any modification requirements to the study team.

Exception Requests that include use of a Short Form Consent Process:
If a study team seeks to enroll a single subject who does not speak the language the main consent form is written in, the study team may request to use an Informed Consent Short Form via an Exception Request. Exception requests for short forms must include:

- A completed Exception Request Form
- A copy of the translated Penn IRB English Short Form Template that includes all required elements
- Certification of translation from a native speaker or translation service
- Information about who will serve as a translator whenever the study team discusses the study with the subject

During the review of the exception request for short form use the Screener should assess:
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES
5.9 Exception Requests & Short Form Consent Process

- Whether the submission includes all the required documentation
- Whether all elements of consent are present in the short form
- Who the request is for and the circumstances which prompted the need for the short form use
- An appropriate plan is in place for ensuring a translator will be available to go over the full study consent form with the non-English speaking subject at the time of the initial consent process, as well as ongoing subject participation throughout the remaining duration of the subject’s participation in the study.
- The short form is designated for one-time single subject use only in the event a non-English speaking subject is identified as being eligible for the study when the study does not anticipate targeting non-English speaking subjects. In the event that non-English speaking subjects will now be targeted, a modification would be required for approval of a fully translated consent form in the language of that non-English speaking demographic would be warranted along with appropriate revisions to the protocol and HSERA application eligibility criteria.
- If multiple exception requests for use of short forms in the same foreign language are received for the same study, the IRB may require revisions to the protocol and translation of the main consent form to eliminate the need for further exceptions.

When a letter is drafted for an exception that includes a short form, the PDF copy of the short form should be stamped in a similar manner as a consent approved with a modification with additional text to make it clear that the short form is approved for a single subject:

ONE-TIME USE ONLY
IRB Approved From: 01-10-2019 To: 05-31-2019

DOCUMENTATION OF THE REVIEW

HSERA
- Comments should be added to HSERA to provide the completed screening notes and letter drafting instructions, any email correspondence related to the review and any documents related to the review received from the study team outside of HSERA
- Text only comments regarding details of the review may be added at the FINAL reviewer’s discretion.
- Expedited Exceptions should be assigned to whatever Board is identified on the summary page in PennERA Unless Chair review is required then it should be assigned to the Board associated with the Chair reviewer.
- If any submissions assigned to PennERA are returned, the PennERA determination for that action should be set to “Issue Identified”. Any subsequent returned submissions that appear in PennERA should also be set to “Issue Identified”. Only the submission which is assigned for final approval should reflect a “Pending” status.

PAPER
- Upon completion of the screening, the completed worksheet and any email correspondence with the study team should be printed and attached to the study file along with the full packet of submitted paper documents.
- The study file and documents should be placed together on the signing desk for IRB Director final review

PENN ERA
Summary Page- Review and approval of exception requests should not result in any changes to the information on the Summary page.
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES
5.9 Exception Requests & Short Form Consent Process

Agenda Notes General Review Page Data Entry – Be sure to fill in:
- Confirmation code (for HSERA submissions place the HSERA confirmation code. For paper place the Submit date)
- Submit Date
- Accurate Review type (Exception)
- For paper submissions the review activities should be completed for each step of the assignment workflow
- Description field data entry should identify whether the submission is paper or electronic and include a summary of the exception request
- A complete document list may be required. Please follow screener instructions. The HSERA application should always be listed even if a complete document list is not required
Letter Drafting Review Details Page Data Entry - Be sure to fill in and VERIFY:
- Correct Review Category (always expedited)
- Board Name
- Agenda Radial (YES)
- Agenda Date (Next available –Never in the past)
- Review meeting date (Always same as determination date)
- IRB Reviewer (Must be an IRB Director or Chair)
- Determination (should be either Approved or Acknowledged)
- Determination Date (always same as review meeting date)
- The same document list from the agenda page should be entered into the Comments field on this page.
- Please follow screener instructions for notes in the Comments and Provisions fields
- Please draft a letter using the Expedited Modification Approval OR Acknowledgement template.
OVERVIEW
This section outlines procedures and guidance for conducting and documenting expedited reviews of Reportable Adverse Event Submissions. The IRB will accept reports when the investigator is unsure whether the event meets the expedited reporting criteria. The IRB will review these reports to determine whether the event qualifies as a reportable event requiring convened review. Reportable event submissions for both Paper and Electronic Studies should be submitted through the HS-ERA electronic submission system. Paper documents may be accepted in certain circumstances in order to facilitate review.

The workflow for all Expedited Reportable Events follows the workflow outlined in section 4.1 of the GDO.

PROCEDURES
Upon receipt of a Reportable Event submission assignment (both paper and HSERA) the screener (Usually a Senior IRB administrator) utilizes the Reportable Event Checklist to assess completeness of the report.

The assessment of the report should determine:

- Completeness of the submission. The requirements for submitting Reportable Events are fully described in the Reportable event submission form that is required to be completed by the study team
- Whether the submission contains enough information to determine if the event meets the IRB’s event reporting criteria.
- Whether the study team has detailed an appropriate corrective action plan
- Whether any study documents should be revised in response to the event
- Whether the report qualifies for Expedited acknowledgement or requires convened review for assessment as an unanticipated problem involving risks to subjects or others

Every screening should begin with the most recent version of the blank checklist. Template copies of this checklist is available on the shared G drive. PennERA, HSERA, and any relevant attachments should be referenced while screening the report.

If inadequate information is provided to determine whether the event meets the reporting criteria, the screener should request additional information from the investigator. The screener should not return the submission to the study team in HS-ERA. Additional information should be solicited via email in order to facilitate timely consideration of the event. The screener may consult with the IRB Director, Associate Director, Assistant Director, or IRB Chair(s) in order to determine the appropriate course of action for reviewing the event.

When the screening assessment is complete the screener will assign the submission for Acknowledgement by the IRB Director or Chair in PennERA. Once the report is acknowledged there are two pathways that may occur:

1. The event was determined not to meet the reportable event criteria and drafting the acknowledgement letter is the final step in the process

2. The event was determined to require convened review. The Acknowledgement letter will include a note informing the study team that convened review will take place. The letter may also include request for additional supporting documentation be provided via email in advance of the convened meeting date. Procedures and Guidance for Reportable Events that require convened review are discussed elsewhere in the GDO.
GUIDANCE
- If an event is found to require convened review, the screener should inform the IRB administrator for the board at which convened review will take place as soon as possible and ensure all applicable documentation is available in HSERA. Consistent communication regarding completion of the expedited acknowledgement and scheduling of the separate convened review is crucial to ensure timely review of the event.

- Reportable Events may be submitted as either Medical or Non-Medical events. There are separate submission forms available depending on the type of event however all events are screened using the same criteria.

- The Reportable Event screening checklist includes important definitions and criteria for assessing events. Please see the checklist for details of conducting the screening.

- For events that are submitted which do not meet reportable event criteria, it may be necessary to educate the study team via email or informative note in the letter to ensure appropriate reporting in the future. While the IRB is willing to assist with the determination of reporting requirements it is important for research teams to be aware of the regulations so as not to over report and over utilize limited IRB resources.

DOCUMENTATION OF THE EXPEDITED REVIEW

HSERA
- Comments should be added to HSERA to provide the completed screening worksheet with notes and letter drafting instructions, any email correspondence related to the review and any documents related to the review received from the study team outside of HSERA

- Text only comments regarding details of the review may be added at the reviewer’s discretion.

- Event submissions assigned for Director review should be assigned to whatever board is identified on the Summary page for the study

- Event submissions assigned for Chair review should be assigned to the board associated with the designated Chair.

PAPER
- Upon completion of the screening, the completed worksheet and any email correspondence with the study team should be printed and attached to the study file along with the full packet of submitted paper documents.

- The study file and documents should be placed together on the signing desk for IRB Director final review

PENN ERA
Summary Page- Expedited Review of reportable events should not result in changes to the summary page.

Agenda Notes General Review Page Data Entry – Be sure to fill in:
- Confirmation code (for HSERA submissions place the HSERA confirmation code. For paper place the Submit date)
- Submit Date
- Accurate Review type (AE- Serious or Unanticipated Adverse Events)
- For paper submissions the review activities should be completed for each step of the assignment workflow
- Description field data entry should identify whether the submission is paper or electronic and include a summary of the event

-Additional fields on the AE Detail page will automatically populate with data entered in HSERA
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES
5.10 Reportable Adverse Event Submissions

- A complete document list may be required. Please follow screener instructions. The HSERA application should always be listed even if a complete document list is not required

**For Reportable Events that are referred for convened review, a secondary review must be created by clicking the blue Add button on the Grey Reviews ribbon. The Board should be assigned as whichever board will conduct the review. This will create a separate letter drafting review page for the convened action. The same agenda notes review page will be used for both the expedited acknowledgement and the convened review. The screen shot below demonstrates that the Full Board review has the radial button selected so that it becomes the final review once the expedited acknowledgement letter has been drafted and sent to the study team. Additional revisions to the Agenda notes page will be required to prepare for the convened agenda. Please see the Convened Deviations GDO for more details.

Letter Drafting Review Details Page Data Entry (For Expedited Acknowledgement only)- Be sure to fill in and VERIFY:
- Correct Review Category (always expedited)
- Board Name
- Agenda Radial (YES)
- Agenda Date (Next available –Never in the past)
- Review meeting date (Always same as determination date)
- IRB Reviewer (Must be an IRB Director or Chair)
- Determination (always acknowledged)
- Determination Date (always same as review meeting date)
5.10 Reportable Adverse Event Submissions

- Please draft a letter using the Amendment Acknowledgement template.
- If the Event Report is being scheduled for convened review a note should be placed in the letter to inform the study team such as “Receipt of this report has been acknowledged. It has been referred for convened review by IRB # on DATE for assessment.”
OVERVIEW
This section outlines the processes for screening and documenting review of submissions which serve to respond to stipulations raised by the Convened IRB that are eligible for expedited review. Responses that qualify for expedited review are the result of convened review determinations of Withheld or Conditional approval where all stipulations are communicated in a directive manner with clear instructions on how to address the stipulations. Any stipulations raised which are open ended or call into question the criteria for approval (Tabled or Disapproved submissions) do not qualify for expedited review and are discussed elsewhere in the GDO.

All new research studies are required to be submitted via HSERA therefore all responses to stipulations raised during Initial review will be received via HSERA. Most existing studies reviewed by the Convened Board will also be received via HSERA. However it is possible that Modifications and Continuing Reviews for studies documented on paper may still be reviewed by the convened board. Notes for documentation of responses to stipulations raised for paper studies is also provided.

Response to stipulations submissions follow the same workflow for expedited assignments outlined in GDO section 4.1

PROCEDURES
Upon receipt of a response submission in HSERA or paper, the screener will utilize the Response to Stipulations Checklist to assess the response for completeness. Assessment of completeness requires review of the updated HSERA application, all attachments / study documents in question and the IRB Determination letter which communicated the stipulations to the study team. Usage of the Response to Stipulations Checklist is universal for all types of responses (Initial, Modification, Continuing Review, Reportable Event, Deviation, and Exception).

Within the checklist the screener should

- Clearly Identify of the original submission that is being responded to
- Create a complete list of all stipulations raised during the review of the original submission as they appear in the determination letter for the original submission
- Below each stipulation the screener should clearly summarize the response provided by the study team and include any comments or questions that should be brought to the final reviewer’s attention
- Provide a separate assessment of any additional unsolicited revisions that the study team may have included with the submission
- Provide clear instructions for data entry and letter drafting.

If during the screening process the screener concludes that the response is incorrect or incomplete, those issues should be addressed with the study team prior to placing for final approval. Depending on the nature of the issues, the screener may opt to return the response submission for additional revisions or address the issues via email. Instructions for returning submissions is available elsewhere within the GDO.

Please note that Paper submissions cannot be returned so all issues should be addressed via email until the response is ready for final approval.

If no issues were noted or if the issues raised have been resolved, the screener should assign the final review to either an IRB Chair or IRB Director. Selection of the final reviewer should be made based on the nature of the stipulations and complexity of the related responses.
- During the assessment of the response, the screener should determine whether expedited review of the response is appropriate. It is possible that the study team may have included responses or additional substantial changes that were not expected or requested by the IRB. Any significant unexpected changes included with a response should be discussed with a Senior Administrator or Director prior to placing for expedited approval. If Expedited review cannot be completed, the submission should be screened and prepared for convened review.

- At times, a study team or sponsor may decline to make the requested directive revisions outlined in a stipulation. As part of the screening process, the screener should assess whether the rationale provided for not complying with a directive stipulation is appropriate. If no rationale is provided the submission should be returned if possible. Screeners should seek senior administrator, Director or IRB Chair guidance to determine if a rationale for not complying with an IRB stipulation is appropriate prior to placing for final review.

- Documenting the approval of documents across responses is the responsibility of the screener and requires multiple lists identifying approval of documents according to the confirmation code or date of submission with which they are approved. The Response to Stipulations checklist is set up to include 2 lists (one to list documents that were “approvable” with the original submission and one list to capture approval of revised and new documents submitted with the first response). Depending on how many times a submission is reviewed and returned, more separate lists may be required.

- The topmost document list should be the only list which includes the HSERA Application since all previous applications were returned they cannot be considered approved

- Documents should only be listed ONCE. An individual document should not appear in multiple lists. For example, the document listing shown below is incorrect because it names the consent form in both lists. Since the consent form was the document related to the only stipulation for this review the version reviewed on 12/19/2018 is NOT approved. Only the version submitted with the response is approved. Thus the consent form included with the response should listed and the consent forms mentioned from the original submission should be removed.

The following documents were included in the response:
- HSERA Response Submission, confirmation code: xxxxxx, submitted on 01/15/2019
- Response Cover Letter, dated 1/15/2019
- Consent Form tracked changes version 14Nov2018
- Consent form Clean version 14Nov2018

The following documents, submitted under code: (xxxxxxxx), were previously reviewed by the IRB on 12/19/2018 and are now approved:
-IRB Modification Form [Modification Form_03Dec2018]
-Cover letter dated 12/3/18
-Patient brochure [Brochure102_V2_CountryCode_Language_FormattedTemplate]
-Patient emergency card track change [PatientEmergency_CountryCode_Language_V3_TrackChange]
-Patient emergency card clean [PatientEmergencyCard_V3_CountryCode_Language_FormattedTemplate]
-New protocol [SYNT001-102_Protocol Amendment 5_Final_23Oct2018]
-New protocol summary of changes [SYNT001-102_Protocol Amendment 5_Final_23Oct2018_SOC]
-New protocol track changes [SYNT001-102_Protocol Amendment 5_Final_23Oct2018_TC]
-Consent form tracked changes [SYNT102_107_14Nov2018]
-Consent form clean [SYNT102_107_14Nov2018_jw_clean]
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES
5.11 Expedited Responses to Convened Review

UPDATING THE SUMMARY WITH RESPONSES:

Response to Initial Review (AKA Response to Withheld Initial)
The following fields **will definitely require revision** when approval is granted for a response to withheld initial:
- Determination (Change from Withheld Approval to whatever the new status is – Approved, Approved Contract Pending, etc...)
- Determination Date (change to align with the review date of the response)
- Approved From (Change to align with the review date of the response)

The following fields **MAY require revision** when approval is granted for a response to withheld initial:
- Review Category
- Risk Level
- Short Title, Full Title, PI, Sponsor, personnel (depending on changes submitted with the response)

The following fields **should NOT change** when approval is granted for response to withheld initial:
- Submitted on Date
- Initial Submission Date
- Original Meeting Date
- Research Type
- Approved TO Date

Response to Modification Review (AKA Response to Withheld Modification)
There are **NO fields on the summary page that should be updated with the approval of response to withheld modification.** Unless the modification made changes to the title, PI, study staff, or other information captured at the bottom of the summary page- those changes should be made by the screener. Letter drafters should consult with the screener prior to making any changes to the summary page while working on a response to withheld modification.

Response to Continuing Review (AKA Response to Conditional Re-Approval)
The following fields **will definitely require revision** when approval is granted for a response to Conditional Re-approval:
- Determination (Change from Conditional Re-Approval to whatever the new status is – Approved, Approved (No CR), etc...)
- Determination Date (change to align with the review date of the response)
- Approved From (Change to align with the review date of the response)

The following fields **MAY require revision** when approval is granted for a response to Conditional Re-approval:
- Review Category
- Risk Level
- Short Title, Full Title, PI, Sponsor, personnel (depending on changes submitted with the response)

The following fields **should NOT change** when approval is granted for response to Conditional Re-approval:
- Submitted on Date
- Initial Submission Date
- Original Meeting Date
- Research Type
- Approved TO Date
DOCUMENTATION OF THE REVIEW

HSERA
- Comments should be added to HSERA to provide the completed Response to Stipulations screening checklist with screener notes and letter drafting instructions.
- Comments should be added to HSERA to provide any email correspondence related to the review and any documents related to the review received from the study team outside of HSERA.
- Text only comments regarding details of the review may be added at the reviewer’s discretion.
- The submission should be assigned to the same Board that reviewed the original submission and raised the stipulations.
- Any submissions assigned to PennERA that resulted in being returned to the study team should be marked “issue identified”. Only the final submission placed for approval should be set to “Pending”.

Paper
- Paper responses assigned to board chairs should be sent via email. All submission documentation, the finalized Response to stipulations checklist, any study team email correspondence should be compiled and forwarded to the chair for review. The IRB Chair email response with determination should be used to document the approval.
- Paper responses assigned to a Director should be placed on the signing desk. All submission documentation, the finalized Response to stipulations checklist, any study team email correspondence should be printed and placed with the study file on the signing desk for Director Signature of approval.

PENN ERA (Penn ERA documentation is the same for HSERA and Paper responses)

Summary Page- the summary page should be checked for accurate data entry at the time of assignment for final review of any submission as well as upon completion of letter drafting for any submission. In the context of responses, changes to the summary are discussed above. Generally, research that requires response to stipulations is Greater Than Minimal Risk research. The Summary page for GTMR research should always have every field completed with the exception of any fields in the “other Information” section that are not applicable. The fields shown here are most important:
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES
5.11 Expedited Responses to Convened Review

Agenda Notes General Review Page Data Entry – Be sure to fill in:
- Confirmation code
- Submit Date
- Accurate Review type for Responses (Response to Initial, Response to Continuing Review, Response to Amendment)
- For paper submissions the review activities should be updated at each step of the assignment workflow
- Description field data entry identifying this as a response to stipulations. There is specific language to use which should be included in the screening worksheet. Complete document list is also required

Letter Drafting Review Details Page Data Entry- Be sure to fill in and VERIFY:
- Correct Review Category (always Response to Conditions)
- Board Name
- Agenda Radial (YES)
- Agenda Date (Next available – Never in the past)
- Review meeting date (Always same as determination date)
- IRB Reviewer (Must be an IRB Director or Board Chair)
- Determination
- Determination Date (always same as review meeting date)
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES
5.11 Expedited Responses to Convened Review

- Risk Level
- Date from (same as determination date)
- Date To
- Insert Document list and any notes into Comments field.
- Prior to drafting the letter you may need to update the summary. Check instructions above based on the type of response you are drafting to be sure the summary is updated appropriately.
- Please draft a letter using the appropriate response letter template:
  Response to withheld Initial = Initial Approval Cond. Met letter template
  Response to withheld Modification = Amendment Cond. Met
  Response to Conditional Re-Approval = Continuing Review Cond. Met

Guide to Daily Operations V. 10
UPENN IRB
OVERVIEW
This section outlines procedures and guidance for conducting and documenting review of closure submissions. Closures are received via HSERA and paper after the research has been completed to close the IRB record. The workflow for all Closure Reviews follows the workflow outlined in section 4.1 of the GDO.

PROCEDURES
Upon receipt of a closure submission assignment (both paper and HSERA) the screener utilizes the Closure Checklist to assess completeness and appropriateness of the closure request. Every screening should begin with the most recent version of the blank template. Template copies of these checklists are available on the shared G drive.

The checklist includes specific areas of assessment for the application and submitted documents. The IRB screener should determine whether the closure request is appropriate. Requirements for closing research applications are outlined within the submission form that must be completed by the submitting study team. The requirements for approval of a Closure are outlined in the checklist. The checklist should be completed with adequate notes to assist the final reviewer in determining whether approval for completion may be granted.

If the IRB screener determines the submission is incomplete or not yet ready to be reviewed, the submission is returned to the submitter for revision without approval. If minor issues are identified, they may be addressed with the study team via email when appropriate. Paper submissions cannot be returned. The IRB screener should work with the study team via email to rectify any issues with the submission.

If no issues were noted during the review or if the issues raised by the IRB screener have been resolved, the review should be appropriately documented and the submission should be assigned to an IRB Director for final review.

The final reviewer reviews the application to determine if the criteria for closure have been met. If any questions or concerns related to the criteria for closure are identified, the approver communicates these issues to the IRB Screener. At this time, the submission may be returned for revisions or issues may be addressed via email.

GUIDANCE
- Closures for Industry sponsored research should be forwarded to the IRB Business Administrator to confirm that all IRB billing is complete prior to placing the submission for approval. An email should be sent with the details of the research protocol. The confirmation email from the Business Administrator should be attached to HSERA or included with the study file for paper studies.

- Closures for industry sponsored research require documentation from the sponsor that the close out visit is complete and that IRB closure is appropriate. If this information is not yet available the study cannot be closed.

- Closure submissions may not include modifications. If any unapproved content is included with a closure the Screener should work with the study team to determine if those documents should be removed or if a separate modification is required prior to closure.

- Closure submissions may be accepted via email and in some cases when an investigator leaves the institution the IRB may be asked to close all studies related to that investigator without individual submissions. IRB Directors should be involved in any email request or request for closure of multiple studies without individual submissions.
5.12 Closure Submissions

DOCUMENTATION OF THE REVIEW

HSERA
- Comments should be added to HSERA to provide the completed screening worksheet with notes and letter drafting instructions, any email correspondence related to the review (including Billing email) and any documents related to the review received from the study team outside of HSERA.
- Text only comments regarding details of the review may be added at the FINAL reviewer’s discretion.
- Closures should be assigned to whatever Board is identified on the summary page in PennERA.
- If any submissions assigned to PennERA are returned, the PennERA determination for that action should be set to “Issue Identified”. Any subsequent returned submissions that appear in PennERA should also be set to “Issue Identified”. Only the submission which is assigned for final approval should reflect a “Pending” status.

PAPER
- Upon completion of the screening, the completed worksheet and any email correspondence with the study team should be printed and attached to the study file along with the full packet of submitted paper documents.
- The study file and documents should be placed together on the signing desk for IRB Director final review.

PENN ERA

Summary Page - The summary page should be updated when the letter is drafted to change the determination to “Completed” and to update the determination date. Approved From and Approved TO should be BLANK.
UNIT 5 – EXPEDITED IRB REVIEW PROCEDURES
5.12 Closure Submissions

**Agenda Notes General Review Page Data Entry – Be sure to fill in:**
- Confirmation code (for HSERA submissions place the HSERA confirmation code. For paper place the Submit date)
- Submit Date
- Accurate Review type (Review – Report of Completion)
- For paper submissions the review activities should be completed for each step of the assignment workflow
- Description field data entry should identify whether the submission is paper or electronic and note “Study Closure”
- A document list is not required. Listing the HSERA application is not required.
### Letter Drafting Review Details Page Data Entry - Be sure to fill in and VERIFY:
- Correct Review Category (always expedited)
- Board Name
- Agenda Radial (YES)
- Agenda Date (Next available – Never in the past)
- Review meeting date (Always same as determination date)
- IRB Reviewer (Must be an IRB Director or Chair)
- Determination (always Completed)
- Determination Date (always same as review meeting date)
- Date From (BLANK)
- Date To (BLANK)
- Provisions and comments should be BLANK
- Prior to drafting the letter you must update the summary. When the Update Summary fields appear you must update the Determination, Determination Date, Approved From, and approved to fields.

![Expedited Review Details](image-url)

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<table>
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[Update Summary]
UNIT 6
CONVENED IRB REVIEW PROCEDURES

6.0 Convened Assignment Workflow
6.1 Convened Board Management
6.2 Convened Initial Reviews
6.3 Convened Continuing Review
6.4 Convened Modifications
6.5 Convened Deviation Reports
6.6 Convened Exception Requests
6.7 Convened Adverse Event Reports
6.8 Community Based Research / Exception From Informed Consent (EFIC)
6.9 Convened Responses to Convened Reviews

Back to Main Table of Contents
OVERVIEW
This section describes the workflow for all actions received by the IRB that require convened IRB review. The majority of submissions received by the IRB are electronically sent through the HSERA system. Paper submissions are also described in this section. This process applies to Initial, Modification, Continuing Review, Deviation, Exception, and Reportable Events that require convened review.

The Assigner may be an IRB Director or authorized designee. The Screener may be either the administrator or assistant/coordinator for the particular board. The Final Reviewer must be one of the IRB Directors or an IRB Board Member. Additional information about appropriate scheduling, screening and review of convened actions is available in other sections of the GDO related to Convened Review.

PROCEDURES
1. Receipt
   a. The submission is received in the HS-ERA IRB queue once approved by the Principal Investigator and Department Chair as required.
      i. All initial submissions require both PI and Dept. Chair approval prior to IRB receipt
      ii. Any subsequent submissions require only PI approval prior to IRB receipt (response to initial, modification, continuing review, exception, deviation)
      iii. Submissions returned by the IRB to the study team via HSERA using either “return for response without approval” or “return for revision without approval” do not require PI approval or Chair approval when the response/revision is re-submitted
   b. Upon receipt in the IRB queue, the status of the submission is automatically changed from “Pending review by (Principal Investigator’s or Department Chair’s name)” to “Accepted and submitted for review”.
   c. Paper submissions are received by the front desk staff. The submission is manually added to PennERA by front desk staff by utilizing the Add New field in the submissions page or by creating a new protocol and updates the review activities page to reflect the receipt of the submission. The documents provided by the submitter are date stamped and grouped with the most recent study file folder and placed on the assigning desk
2. Assigning
   Assigning actions that require convened review follow the same logistical process as expedited assignments with the following exceptions:
   a. Actions that qualify for Convened review are assigned according to the following logic:
      i. Initial applications are assigned to the administrator of the board with appropriate expertise for the protocol subject (agenda availability is also consideration)
      ii. Modifications are assigned to the administrator of the board with upcoming agenda availability (appropriate board expertise is also a consideration)
      iii. Continuing reviews are generally assigned only to the Coordinator of the same board that reviewed the initial application (expiration date of the study is also a consideration)
      iv. Reportable events, Deviations and Exception requests are assigned to the administrator of a board that either has expertise with reviewing previous actions for that protocol OR has expertise of the protocol or submission details.
   b. The assigner uses the assign field for the submission and adds a comment to the submission.
      i. It is at this time that the assigner should alert the screener that the submission should be scheduled for convened review.
      ii. It is not uncommon for a submission assigned for convened review to be referred for expedited review based on thorough assessment of content. It is ultimately the screener’s responsibility to verify required level of review.
   c. Paper submissions gathered on the assigning desk are organized and assessed by the assigner. The assigner applies the same scrutiny to paper study documents to determine level of review required. The assigner makes a physical note on the file detailing the Board that should review the action. The same
assigning rules apply to paper as HSERA, however the documentation for the submission will be only on paper and grouped with the physical file. The file is then placed on the desk of the IRB staff person who is assigned to process it.

d. Email Submissions – Generally the IRB does not have a mechanism for receiving emailed submissions (there are few exceptions). If a study team reaches out to an individual member of the staff and arranges for submission of a single action via email this may be accepted.
  i. If the emailed submission received is for a study that is documented on paper, the contents will be printed, stored with the file and processed as if it were received via traditional mail or drop off. Contents of email submissions may also be uploaded to PennERA as attachments for documentation.
  ii. If the emailed submission received is for a study that is documented in HSERA, the IRB may process it and require a follow up HSERA submission to complete the regulatory file. Contents of email submissions may also be uploaded to PennERA as attachments for documentation.

3. Screening
a. The screener receives a notification email detailing the assignment and information for full board scheduling. If the submission is for Initial review, the screener should assign the action to the appropriate board in PennERA right away to generate a protocol number and to ensure the Bio/HRPP page responses send appropriate pings to ancillary committees as soon as possible.

b. The screener then conducts a thorough screening of the action by utilizing the appropriate submission screening checklist. Specific information about submission screening is discussed in other sections of the GDO.

c. Upon completion of the screening, the issues identified should be addressed by one of the following methods:
  i. Request for clarification from the study team via email in advance of the meeting
  ii. Returning the submission if it is incomplete or not yet ready to be reviewed. A deadline for resubmission should be provided to the study team. The response submission will be reassigned to the same administrator upon receipt to continue preparation for agenda scheduling
  iii. Addition of administrative stipulations to the Agenda to be addressed by the study team in response to IRB review. Administrative stipulations accepted by the board will be inserted into the IRB determination letter sent to the study team after the meeting.

d. At any time during screening, consultation with senior administrators or Regulatory Representatives for guidance regarding the appropriate approach for issues identified or determining whether convened review is required may be necessary.

e. If at any point in the above processes, the IRB Administrator, Senior Administrator, or Regulatory Representative determines that the study is eligible for expedited IRB review, the study is then reviewed according to the procedures described in GDO Unit 5.

f. Paper submissions are placed on the screener’s desk area by the assigner. The screener conducts a thorough screening utilizing the appropriate submission screening checklist. Copies of the finalized checklist and any emails are compiled in a PDF portfolio. When the agenda for the meeting is sent to the Board members via email, the portfolio of documents is also attached. The same screening rules apply to paper as HSERA, however the documentation for the submission that would normally be in HSERA will be on paper and grouped with the physical file.

4. Scheduling, Member Assignment and Pre-meeting Review
a. If no issues were noted during the screening or if the issues raised by the screener have been resolved, then the submission is assigned to the appropriate board and member in PennERA in preparation for producing the meeting agenda

b. Once the action appears in the Submissions page of PennERA, the screener must complete all necessary data entry for the agenda and assign a board reviewer. Member assignments are made in PennERA on the Review Details page (the same process as assigning a final reviewer for an expedited action). For Full
UNIT 6 – CONVENED REVIEW PROCEDURES

6.0 Convened Assignment Workflow

board reviews the assignment grants access to the action by the members in HSERA and to indicate on the agenda document who is tasked with reviewing each action.

c. Once all agenda items have been screened and scheduled, the agenda is finalized and sent to the members (~ 10 days in advance of the meeting date). Instructions for building agendas are described elsewhere in the GDO.

d. If any responses are for paper studies, the documents (including any documents that would be attached to HSERA for an electronic submission) should be compiled into a PDF and forwarded to the board members via email and printed for the physical file.

e. IRB staff will be in regular communication with the members for issues identified before the meeting. The IRB staff should encourage and assist IRB members with addressing preliminary concerns by reaching out to the study team or providing administrative clarifications.

f. Pre-meeting correspondence with IRB members or the study team should be shared with the primary, secondary and IRB chair. Pre-meeting correspondence should be uploaded to HSERA for reviewer reference.

g. The Agenda tracker on the G Drive is consistently updated to track issues and their resolutions until the day of the meeting

h. IRB Members are also asked to inform the IRB staff if they are conflicted on any of their assignments upon receipt of the agenda. Any identified conflicts should result in re-assignment to a different board member.

5. Convened Meeting Review

a. Final review of convened actions takes place at a scheduled in-person IRB meeting. For all voting actions, the IRB Administrator and Assistant are present at the meeting to take notes and ensure a quorum is present for each discussion and vote.

b. The role of the IRB Board Member is to review the protocol submission to determine if the criteria for approval have been met, assess the protocol for any controverted issues and raise the issues for discussion during the meeting, along with their resolutions, and vote on the risk assessment and final review decision.

c. The regulatory representative is a senior member of the IRB staff (typically the Director or Associate Director) who serves as an IRB Board Member. In addition to Board Member duties the Regulatory Representative also provides expertise on federal regulations and Penn policy and provides guidance in order to ensure that policies are applied consistently across all Penn Boards. The regulatory representative also aids the IRB administrator by discussing potential issues prior to the meeting and reviewing minutes and letters generated after the meeting.

d. The IRB Administrator and Administrative Coordinator take notes during the discussion of the review. The notes taken include the order of review, an overview of the review discussion by the Board, including a summary of the proposed protocol design, any controverted issues and their resolutions, assessment of risk determination, and final decision with vote counts.

e. Any IRB members who are conflicted on a particular review must disclosed this information at the beginning of the meeting and recuse from the meeting room for the duration of the review discussion and vote. The minutes must reflect recusal of individual members for conflict.

f. Notes may be taken in an Agenda style document generated in PennERA before the meeting, or in a separate self-made document if preferred. The document should be organized to clearly indicate the notes for each individual action on the agenda.

g. At the conclusion of the meeting the IRB Administrator collects any notes and/or marked documents provided by the members to supplement the minutes taken during the Board’s discussion of the protocol.

6. Post Meeting Wrap up - Minutes

a. After the meeting is over, the Board Administrator and Coordinator work to draft finalized minutes for each action based on notes taken at the meeting, as well as any notes or marked documents provided by the members.
b. The information that is captured in the minutes should mirror the Board’s discussion and concerns. The minutes are not a transcript of the Board’s discussion but rather a summary of the discussion including descriptions of controverted issues raised by members and the resolution of those issues. Unless the submission is tabled or disapproved, stipulations and recommendations should be directive statements written to the study team informing them how to revise their submission to meet the Board’s requirements.

c. Stipulations related to tabling or disapproval may be open ended questions or requests for additional information/documentation.

d. Stipulations for consent forms may be provided to the study team in a copy of the consent form using comments and tracked changes.

e. Generally, the Administrator for the Board is assigned to draft minutes for all initial actions, reportable events, and other complex actions. The Coordinator for the Board is assigned to draft minutes for all continuing reviews, modifications and any additional actions that the Board Administrator finds appropriate based on level of complexity. The Administrator is tasked with proof reading the minutes drafted by the coordinator prior to drafting any letters with stipulations or entering the minutes into PennERA.

f. While the minutes are finalized, the IRB staff should review the comments section of HSERA for each action from the meeting to remove any reviewer comments and any uncontrolled documents. The IRB screening checklists and accepted meeting minutes should be the official record of IRB review.

g. Finalized minutes are copied into PennERA provisions for each action. A final document is generated which compiles all the minutes for all the actions reviewed at the meeting. A PDF copy is sent to the board prior to the next convened meeting for review and acceptance. Once accepted, the final copy is archived on the G: Drive in the IRB Minutes folder.

7. Post Meeting wrap up - Determination Letter

a. Upon finalization of the meeting minutes, all submissions reviewed by a convened IRB will have a letter drafted and forwarded to the study team within 2-3 days of the meeting date.

b. The Administrator for the Board is assigned to draft letters for all initial actions, reportable events, and other complex actions.

c. The Coordinator for the Board is assigned to draft letters for all continuing reviews, modifications and any additional actions that the Board Administrator finds appropriate based on level of complexity.

d. The procedures for convened letter generation generally align with the instructions provided in GDO section 4.6.

e. For all convened actions, the final copy of each letter should be uploaded to HSERA, PennERA and emailed directly to the study team.

f. Once the letters are distributed, some submissions may need to be returned depending on the outcome.

   i. Submissions that are tabled by the Board are returned for “response with approval.”

   ii. Submissions that receive withheld approval are returned for response without approval.

   iii. Submissions that receive conditional re-approval are not returned – the study team must submit a separate modification to respond to stipulations.

   iv. Submissions that receive outright approval are not returned to the study team.

Additional information about convened meeting activities is available throughout GDO Unit 6.
OVERVIEW
This section describes an overview of the division of responsibilities that is generally applied for board management as well as details for the procedures involved in convened board management. Management of the 8 review boards involves collaboration of several IRB staff members including IRB Board Administrators, IRB Coordinators, Regulatory Representatives.

PROCEDURES
Board Administrator is generally tasked with the following processes in an ongoing fashion:
- Management of member documentation, training and rosters
- Revising Convened Meeting Dates
- Maintaining meeting agenda trackers on the G;Drive
- Screening initial submissions, modifications and other complex submissions that require convened review
- Review of continuing review screenings conducted by the Board Coordinator prior to member assignment
- Assigning reviewers to agenda items
- Agenda finalization and distribution of required meeting documents to the members
- Engaging with the IRB members, board chair, Reg Rep and study teams to address pre-meeting issues
- Meeting attendance for note taking
- Drafting minutes and letters for initial and other complex submissions that require convened review
- Review of all minutes and letters drafted by the coordinator
- Finalization and QA of minutes

Board Coordinator is generally tasked with the following processes in an ongoing fashion:
- Managing expiration of protocols that require convened review
- Maintaining meeting agenda trackers on the G;Drive
- Member attendance tracking and ensuring quorum, sharing convened meeting dates
- Screening continuing reviews for convened review
- Engaging with the IRB members, board chair, Reg Rep and study teams to address pre-meeting issues
- Meeting attendance for note taking
- Drafting minutes and letters for continuing reviews and modifications or any other action as requested by the Administrator
- Meeting Coordination (Catering orders, reserving meeting location, Set up and cleanup of meeting location)

The Board Administrator and Coordinator work closely together to ensure the above tasks are appropriately completed on an ongoing basis. The Administrator may also choose to delegate additional tasks to the Coordinator as needed based on training. The Coordinator should confer with the Administrator and the Regulatory Rep as needed.

Regulatory Representative
The Regulatory Representative is a senior member of the IRB staff (typically the Director or Associate Director) who serves as an IRB Board Member. In addition to Board Member duties the Regulatory Representative also provides expertise on federal regulations and Penn policy and provides guidance in order to ensure that policies are applied consistently across all Penn Boards. The Regulatory Representative also provides assistance to the IRB Administrator by discussing potential issues prior to the meeting and reviewing minutes and letters generated after the meeting.

GUIDANCE
Management Of Member Documentation, Rosters, And Training
The IRB Administrator for each board must collect and maintain records for each member of their board according to the SOP and other sections of the GDO (confidentiality statement, Conflict of interest statement, CV/Resume). Documentation for members is stored on the GDrive in the IRB Membership folder.

Information about every active member is compiled into a board Roster that must also be maintained and updated each month. Rosters are stored on the GDrive in the IRB Rosters folder. Rosters should be maintained using the general template which includes columns for all required member information.

Every month the IRB directors and senior staff develop a member training (PowerPoint) that is presented to the IRB staff at a general staff meeting. The training is then distributed to the IRB administrators to familiarize themselves in order to present the training to the members at that month’s convened meeting. The training presentation is sent to all board members (whether they will be attending the meeting or not) via email when the agenda goes out. The Administrator may also work with the regulatory representative to present the material at the meeting.

**Maintaining Meeting Agenda Trackers**

All 8 IRB Boards have a dedicated folder on the Gdrive for management of materials for each monthly meeting. The Agenda tracker is an Xcel spreadsheet that is continuously updated by both the board Administrator and Coordinator. The agenda tracker should list each action assigned to be reviewed at a particular meeting along with any other pertinent details. The Agenda tracker is also used by the Directors who make convened level assignments in order to assess agenda volume when making assignments.

In addition to the agenda tracker, the Gdrive folder may be used to house and organize screening worksheets, member comments, drafts of the agenda, the member training and any other materials used for monthly IRB meetings.

**Agenda Finalization and Distribution of Required Convened Documents**

10 days prior to the scheduled meeting, the agenda assignments should have been screened and fully prepared for the meeting. Steps for building an agenda are outlined in a separate GDO section.

The agenda should be generated and finalized as a PDF and sent to the IRB members via email along with:
- a copy of any paper submissions in PDF format
- a copy of the previous months finalized minutes for review
- Power point presentation slides for the IRB member training.
- Any other pertinent guidance documents or determination forms relevant to the meeting

**Managing expiration of protocols that require convened review**

Periodically IRB Board Coordinators should run expiration reports in PennERA to gather a list of protocols that are due to expire over the next 90 days. For each study that is due to expire, the study team should be contacted at least once via direct email informing them that their continuing review is due. Continuing reviews are due approx. 6 weeks prior to the expiration of the study, so reports and emails should be prepared in advance of that due date. This is an ongoing process that Coordinators should work into daily operations wherever possible.

**Example Template email:**

Subject Line – “PI Name, Protocol number – IRB Continuing Review Due”

“Hello,

This is in reference to Dr. NAME’s study under IRB protocol # NUMBER. This study is due to expire on 2.3.16 and will require convened review. Please submit the continuing review to the IRB by no later than Friday 1.8.16.

Thank you”

**Member attendance tracking and ensuring Quorum**

Similar to the Agenda tracker, each board has an Xcel spreadsheet attendance tracker to document which meetings each member is available to attend. A quorum is required at every meeting. If quorum cannot be met, the meeting may need to be rescheduled. The IRB Coordinator should be in routine contact with all IRB members via email or telephone to get
confirmation of attendance for upcoming meetings. If any members are not available, the alternates should be contacted to fill in.

The members should be provided with the complete list of meeting dates for their board as soon as possible after it is finalized (usually in early November of the prior year). If they are unable to confirm all dates at once, follow up is required to confirm when they will attend.

Is there quorum?
In order for convened reviews to be valid, a quorum must be present. If a quorum is not available for a meeting date, you must communicate this to the administrator for the board as soon as possible to address the issue.

What is a quorum?
A quorum consists of a majority of IRB members present to discuss and vote on the convened board actions. Quorum is calculated by the number of members on the board as a whole, not the number of members who are available to attend. Quorum must be at least half of the Committee members plus one.

For example, if there are 14 Committee members on a board, quorum is 8 (7 + 1). If there are 15 members, quorum is still 8. If there are 16 members, quorum is 9. A quorum must also include at least one non-scientist, and one physician.

Notes:
1. For research involving prisoners, the prisoner representative must be present.
2. Alternates share one roster position. If both the member and their alternate attend the meeting, only one can vote and only one vote is counted toward the quorum.

IMPORTANT NOTE: If there is only *one* non-scientist or physician present at the meeting and this person leaves the room, a quorum is LOST.

Revising Convened Meeting Dates
If the date of a convened IRB meeting needs to be changed the Administrator and Coordinator should:
- Obtain Director approval for the change
- Contact the Board members and inform them of the change
- Get confirmation of attendance from members for the new date to ensure quorum
- Adjust member assignments based on updated attendance if needed
- Close the original agenda date and create a new agenda date in PennERA
- Shift all full board items to the new agenda date in PennERA
- Run the minutes in PennERA for the expedited items assigned to the old (closed) agenda date to be included with the minutes built for the rescheduled date for member approval
- Make an agenda based on the new date

If a convened IRB meeting needs to be cancelled the Administrator and Coordinator should:
- Obtain Director approval for the cancellation
- Inform the board members of the cancellation
- Close the agenda for the cancelled meeting
- Shift any full board action items to the agenda designated by the director (either another board’s upcoming agenda or the next month’s agenda as appropriate)
- Run the minutes for any expedited assignments that were finalized on the cancelled/closed agenda. Those minutes should be forwarded to the board along with the agenda for the next month’s meeting
Meeting Coordination (Catering orders, reserving meeting location, Set up and cleanup of meeting location)

IRB Meetings typically take place at:
- The IRB office conference room
- 8030 Maloney at HUP
- 9025 Maloney at HUP
- Pennsylvania Hospital Cheston Conference room

The Coordinator for each board is tasked with contacting administrative support personnel at any location outside of the IRB office to reserve space for the appropriate dates and times. Ideally, the full year of meeting dates will have room reservations established around the same time the meeting schedule is finalized (prior to the beginning of the year).

IRB Meetings are catered and the Coordinator is generally tasked with creating the lunch order. The IRB business administrator should be emailed with a lunch order approximately one week before the meeting. In this email include what food items you will be ordering, the estimated cost, and a list of who will be attending the meeting (including the names of members, IRB staff, and guests). Make sure whatever vendor you choose will be able to deliver the food to the meeting location in advance of placing the order. Typical vendors include Bryce’s catering, Beijing, Axis Pizza, Greek Lady.

At some locations the room must be set up with tables and chairs before the meeting begins. Prior to leaving the meeting space at the end, all lunch materials should be cleaned up and removed and the room should be returned to whatever state it was when you arrived.

If any members will be participating in the meeting remotely, the Coordinator should set up the Verizon conference telephone line or set up a video conference via Bluejeans.

IRB Minutes

After each meeting is over, the Board Administrator and Coordinator work to draft finalized minutes for each action based on notes taken at the meeting, as well as any notes or marked documents provided by the members in advance of the meeting or after the meeting.

The information that is captured in the minutes should mirror the Board’s discussion and concerns. The minutes are not a transcript of the Board’s discussion but rather a summary of the discussion including descriptions of controverted issues raised by members and the resolution of those issues.

Stipulations are developed during the minutes writing process. Each stipulation that is placed in a determination letter should have a dedicated area of discussion within the minutes that clearly indicates how the board came to raise the issue. Unless the submission is tabled or disapproved, stipulations and recommendations should be directive statements written to the study team informing them how to revise their submission to meet the Board’s requirements. Upon receipt of the response, the IRB staff will use the stipulations written to assess whether the study team has addressed them properly. Clear and concise instruction is key to ensuring the study team understands what is being asked of them and to ensuring the IRB staff are able to interpret the response.

Stipulations related to tabling or disapproval may be open ended questions or requests for additional information/documentation.

Stipulations for revising consent forms may be provided to the study team in a copy of the consent form using comments and tracked changes to indicate specifically where a change is needed and what the change should be.
Generally, the Administrator for the Board is assigned to draft minutes for all initial actions, reportable events, and other complex actions. The Coordinator for the Board is assigned to draft minutes for all continuing reviews, modifications and any additional actions that the Board Administrator finds appropriate based on level of complexity. The Administrator is tasked with proof reading all minutes drafted by the coordinator prior to drafting any letters with stipulations or entering the minutes into PennERA.

Once the minutes for a meeting have been finalized, the Administrator is tasked with engaging the Assistant Director for Quality Assessment of the minutes. The approved minutes are then shared with the IRB members via email in alignment with the distribution of the agenda for the following IRB meeting. At the beginning of each meeting the members vote whether the minutes from the previous meeting may be accepted. If so, that version of the meeting minutes is date stamped for IRB acceptance and archived in PennERA and on the shared GDrive in the IRB Minutes folder. The approval and archival process for IRB minutes is crucial for IRB Regulatory Compliance in the event of an external audit.

IRB Determination Letters

Upon finalization of the meeting minutes, all submissions reviewed by a convened IRB will have a letter drafted and forwarded to the study team within 2 -3 days of the meeting date.

The Administrator for the Board is assigned to draft letters for all initial actions, reportable events, and other complex actions.

The Coordinator for the Board is assigned to draft letters for all continuing reviews, modifications and any additional actions that the Board Administrator finds appropriate based on level of complexity.

For all convened actions, the final copy of each letter should be uploaded to HSERA, PennERA and emailed directly to the study team.

Once the letters are distributed, some submissions may need to be returned for response depending on the outcome.

- Submissions that are tabled by the Board are returned for response with approval.
- Submissions that receive withheld approval are returned for response without approval.
- Submissions that receive conditional re-approval are not returned – the study team must submit a separate modification to respond to stipulations.
- Submissions that receive outright approval are not returned to the study team.
OVERVIEW
New human subject’s research protocols that meet Greater than Minimal Risk criteria are screened by experienced IRB administrators or senior administrators. Once a new study is assigned to an administrator to screen for their board, they are responsible for documentation of screening, pre-meeting concerns, IRB meeting minutes, data entry and letter drafting. The workflow for Convened Initial submissions follows the workflow described in GDO section 6.0. This section provides specific guidance and procedures unique to convened initial reviews.

PROCEDURES
Screening-
Screening of full board initial submissions follows the procedures noted in GDO section 6.0 with the following clarifications:

After receipt of the assignment, the IRB Administrator assigns the protocol to the appropriate board in PennERA in order to generate a protocol number and to ensure alerts for Ancillary review offices within the HRPP are sent from HSERA based on the responses on the HRPP page of the application.

The IRB Administrator then conducts the initial screening by examining the HS-ERA application and all submitted documents to determine:
1. That the research requires convened review due to the study design and risks
2. That the assigned board has the appropriate expertise available to conduct the review
3. That the submission contains sufficient information for the Board to consider whether the study meets the criteria for approval.

During the screening process, the IRB Administrator reviews and completes each field of the IRB Initial Full Board Checklist to ensure complete and consistent review of the applicable regulations and institutional requirements and to document the preparation for convened review. The checklist instructions should be followed to identify any necessary administrative stipulations (outlined separately in the Administrative Stipulation Appendix).

Please refer to the most recent version of the Initial Full Board Checklist for complete details and information regarding requirements for preparation. The IRB Administrator should also be aware of any additional worksheets that are required during full board preparations such as:

- Subpart B Worksheet (Research involving Pregnancy/ Fetuses/Neonates)
- Subpart C Worksheet (Research Involving Prisoners)
- Subpart D Worksheet (Research Involving Children)
- Drugs/Biologics Worksheet
- Devices Worksheet
- Department of Defense Checklist
- Department of Energy Checklist
- Department of Education Checklist
- Department of Justice Checklist
- Environmental Protection Agency Checklist
Scheduling & Member Assignment

Scheduling of full board initial submissions follows the procedures noted in GDO section 6.0 with the following clarifications:
If no issues requiring returning of the submission were noted during the initial screen or if the issues raised by the IRB Administrator have been resolved:
- updates the PennERA Summary to reflect any other ancillary reviews required (EHRS, CTSRMC, etc.), funding status (industry sponsored or federally funded), subpart determinations, authorization agreements, and contract status if industry sponsored should be completed
- Initial submissions should be assigned to 2 IRB Member reviewers (A Primary and Secondary reviewer).
  - The Primary reviewer focuses on the criteria for approval and substantial issues
  - The Secondary reviewer focuses on the consent process and consent documents

To assign reviewers for a new study that requires convened review, IRB Administrators should refer to the Board Rosters to identify Members with credentials and experience that match the research under review prior to assigning. Consultation with Senior Administrators or Regulatory Reps may be necessary to identify the appropriate reviewer or determine if an outside consultant reviewer is needed.

Convened Meeting Review
Convened Meeting Review of full board initial submissions follows the procedures noted in GDO section 6.0 with the following clarifications For Initial Reviews:
- The primary reviewer presents their findings followed by the secondary reviewer.
- The Board discusses any issues with the submission raised by the primary and secondary reviewer as well as any potential issues or questions that may be raised by other members of the board.
- The Board must accept the administrative stipulations included in the agenda
- The convened IRB considers the findings presented and decides the for approval, withheld approval, tabling, or disapproval of the protocol.
- The convened IRB must assign a risk level to the study
- The convened IRB must determine frequency of continuing review and whether continuing review requires convened review

Post Meeting Wrap up

Post meeting wrap up follows the procedures outlined in the Convened Assignment Workflow GDO section 6.0 with the following clarifications

GUIDANCE
- Approval dates on the summary page of a new Greater Than Minimal Risk study are determined by the date of the initial convened determination and the series of submissions required to reach full approval. For example:
  1. A new study is reviewed by IRB 5 on 2/27/2019 and granted Approval
     a. The Determination Date will be 2/27/2019.
     b. The Approved From Date will be 2/27/2019.
     c. The approved To Date will be 364 days later – 2/26/2020
     d. Unless the contract is pending, Any consent forms will be stamped with approval from: 2/27/2019 To: 2/26/2020
2. A new study is reviewed by IRB 5 on 2/27/2019 and granted Withheld Approval
   a. The Determination Date will be 2/27/2019.
   b. The Approved From Date will be 2/27/2019.
   c. The approved To Date will be 364 days later – 2/26/2020
   d. Consent forms will not be stamped since approval was withheld
      i. When the response to stipulations submission is received and approved,
         - The Determination Date will change to the date the response was approved
         - The Approved From date will be the date the response was approved
         - The Approved To Date will still be 2/26/2020
         - Unless the contract is pending, Any consent forms will be stamped From: the date of response approval TO: 2/26/2020

3. A new Study is reviewed by IRB 5 on 2/27/19 and Tabled. Tabling a study means the board could not make a determination thus:
   a. The Tabled determination date will be 2/27/19
   b. There is no approved from date
   c. There is no approved to date
   d. Consent forms will not be stamped since the study was tabled
      - Response to tabled submissions require convened review. When the response to tabled is scheduled for review the approval dates will either follow the logic of example 1 or example 2 above depending on the outcome of that review.

DOCUMENTATION OF THE REVIEW

HSERA
- An HSERA Comment should indicate which board is reviewing the protocol and on what date
- During screening, Comments should be added to HSERA to provide the completed screening worksheet(s)
- During screening, Comments should be added to HSERA to provide any email correspondence related to the review and any documents related to the review received from the study team outside of HSERA
- Assignment to PennERA from HSERA should occur as soon as possible for all Initial submissions to ensure the ancillary review items on the HRPP page are sent out. If the first submission is returned, the PennERA determination for that action should be set to “Issue Identified”. Any subsequent returned submissions that appear in PennERA should also be set to “Issue Identified”. Only the submission which is assigned to the agenda should reflect a “Pending status”
- During Pre-Meeting review, any email correspondence related to the review should be uploaded to HSERA comments and shared with the assigned reviewers and Board Chair

PAPER – New studies that require convened review must be submitted via HSERA.
**PENN ERA Summary Page** - The summary page should be filled in and updated throughout the screening and final review documentation process. Upon creation of the first submission in PennERA, some information will be pulled from HSERA directly into the PennERA summary fields such as the record number, Review Category, title, objectives and purposes etc. It is the responsibility of the IRB Administrator to ensure that all applicable fields on the summary page are filled in appropriately during screening and meeting wrap up. This includes items on the main summary as well as the supplemental summary pages accessed on the left side menu for documenting Devices, Drugs, Sponsors, and Vulnerable Populations.

The Other Information section at the bottom of the Summary page includes UDFs (User Defined Fields) that are necessary to capture important administrative and regulatory information that is not able to be captured elsewhere. It is the responsibility of the IRB Administrator to ensure all of these fields are updated appropriately during screening and post meeting wrap up.

There is also an area to indicate any significant issues related to a protocol that could affect future reviews. Any notes entered into this area should include:
- Date the note is being placed
- Description of issue
- Conditions under which the note may be removed
- Name of person entering the note
### Agenda Notes General Review Page Data Entry – Be sure to fill in:

- Confirmation code
- Submit Date
- Accurate Review type (Initial Review)
- Description field data entry should be completed with appropriate Initial review agenda notes that align with the following outline:
  - Electronic Submission
  - Confirmation Code:
  - Protocol Description:
UNIT 6 – CONVENED IRB REVIEW PROCEDURES

6.2 Convened Initial Reviews

Notes For Reviewers: (note any special determinations needed like subparts or Devices)

Administrative Stipulations: (include the full list of admin stip identified during screening)

The following Documents are Included with this review:

- HSER A Application, confirmation code: , dated

A complete list of every document being considered by the board is always required with Name of the document, Version and Date. The list should be provided by the study team however corrections may be necessary if the provided list is insufficient.

Letter Drafting Review Details Page Data Entry- Below is an example of data entry required to prepare an action to be added to a convened agenda. The review details and reviewers must be set properly in order for the agenda to populate the correct actions and for the members to be granted access to the action in HSER A. Once the review is complete the Results section will be updated with the outcome, the minutes will be inserted into the Provisions section, the summary will be updated, and a letter should be drafted.
Below is an example of complete data entry for an initial submission that received convened review and was withheld (The most common scenario). During meeting wrap up and letter generation:

- Determinations and all dates should be filled in appropriately
- The Comments field should be completed with the list of stipulations and notes at the top (if any) and the list of included documents
- Provisions field should be completed with the finalized Minutes
- IRB Member attendance and votes should be entered
- Physician and nonscientist Y/N fields must be complete
- The summary should be updated to reflect the outcome of this review
- Once the data entry is complete and the summary is updated, the letter should be drafted.
- One of the following letter templates should be used depending on the determination:
  - HS Initial Approval – Full
  - HS Withheld Approval
  - HS Tabled
6.2 Convened Initial Reviews

**PRIMARY ISSUES RAISED BY THE CONVENED IRB:**
Protocol Stipulations:
1. Please revise the protocol to include guidance on titrating the dose based on weekly blood levels.
2. Please revise the protocol to align with the informed consent regarding the plans for compensation.

Informed Consent and HIPAA Authorization Form

**DISCUSSION:**
The Board was provided a detailed overview of the patient population. The severity and debilitating nature of this rare disease, as well as the high mortality rate were discussed. The lack of knowledge surrounding this disease was noted. The available FDA approved therapy for this disease, as well as off-label treatments, were reviewed. The rationale in support of the use of this product in this patient population was

**Vote Count**
- Yes: 7
- No: 0
- Abstain: 0
- Total: 7
- Recused: 0

**Present Members**
- NICHOLAS
- RUDI
- KAREN
- TIEZTE
- TRACY
- ZIOLEK
- GEORGE
- DOMINGUEZ
- JOHN
- PLASTARAS
- JOANNA
- RHODES
- STEVEN
- BAIR

**User-Defined Fields**
- Physician Present: Y
- Non-Scientist Present: Y
OVERVIEW
Research that is considered Greater Than Minimal Risk (GTMR) requires annual review by a convened IRB. This section describes procedures and guidance for screening and scheduling convened continuing reviews. The majority of active research is submitted electronically via HSERA however some paper protocols are still active. Electronic and paper processes are described together.

PROCEDURES
Screening-
Screening convened continuing review submissions follows the procedures noted in GDO section 6.0 with the following clarifications:

After receipt of the assignment, the IRB Coordinator conducts a preliminary screening by examining the HS-ERA application and all submitted documents to determine:
1. That the research still requires convened review due to the status of enrollment and progress of remaining subjects
   a. Coordinators should be familiar with the criteria for Cat 8a,b,c review and seek Administrator guidance prior to applying the expedited review criteria to a GTMR Continuing Review.
   b. It may be necessary to contact the study team for clarification of subject status and remaining follow up activities to properly make this assessment.
2. The date of expiration to establish which agenda is appropriate for scheduling
3. That the submission is complete (requirements for completeness of a Continuing Review submission are described within the Continuing Review submission form)

During the screening process, the IRB Coordinator reviews and completes each field of the Greater Than Minimal Risk CR Checklist to ensure complete and consistent review of the applicable regulations and institutional requirements and to document the preparation for convened review. A thorough screening of a continuing review requires assessment of all attached documents, the HSERA application and PennERA in context of the checklist instructions. The checklist instructions should be followed to identify any issues.

Any identified issues may result in the submission being returned, querying the study team via email for additional information/ documentation, or agenda notes for the board to consider whether a note or stipulation should be communicated in the determination letter.

The coordinator should consult with the IRB administrator regarding all issues identified during the screening to assess the appropriate course of action. It is the responsibility of the IRB Administrator to do a QA check of each checklist for convened CRs. The checklist should be converted to PDF, signed by the board administrator and attached to the HSERA comments for documentation and Member reference. Any issues identified by the Administrator should be rectified prior to the agenda being released to the Members.

The Agenda Notes should follow the template included in the checklist.

Scheduling & Member Assignment-
Scheduling of convened continuing reviews follows the procedures noted in GDO section 6.0. Convened Continuing Review Assignments are made based what board initially reviewed the protocol, the continuing review submission’s expiration date, and agenda volume.

Convened Meeting Review
Convened Meeting Review convened continuing reviews follows the procedures noted in GDO section 6.0 with the following clarifications:
6.3 Convened Continuing Reviews

- Continuing reviews only have one assigned reviewer (there is typically no secondary reviewer) unless the research is particularly complex.
- The board considers the study progress reported in the submission and whether the information has the potential to alter the most recent risk-benefit assessment. Where progress of specific subjects has the potential to impact the criteria for approval, the Board considers this progress and any follow-up required to ensure the criteria for approval are still met. If complaints have been made about the research, the board considers whether they were appropriately resolved. The board discusses any issues with the submission raised by the primary reviewer as along with any potential issues or questions that may be raised by other members of the board.
- Generally, at the time of continuing review the IRB should refrain from stipulating changes to study documents that have already been approved unless changes are necessary to meet the criteria for approval.
- The Board may recommend any of the following decisions: Approval, Conditional- Reapproval, Suspension, Termination.
- The Board may make a determination that the research qualifies for Cat 9 expedited review going forward.

Post Meeting Wrap up
Post meeting wrap up follows the procedures outlined in the Convened Assignment Workflow GDO section 6.0

GUIDANCE

- If a modification is submitted or is under review at the same time a convened CR is being screened for convened review, the coordinator should consult with the board administrator as well as the IRB staff assigned to the separate submission. If the modification is being reviewed first, the coordinator should assess whether the Continuing Review documents will need to be updated (replaced) with the newer versions prior to agenda scheduling.
- All requirements for continuing review are clearly communicated in the continuing review submission form. Coordinators should carefully review the requirements and communicate any issues in context of those requirements.
- For the Monitoring Committee reporting requirement; the IRB does NOT require submission or summarization of plans/ reports when a study is reviewed by the Penn Abramson Cancer Center DSMC as this is an internal committee and not considered "independent".
- A review that results in Conditional Re-approval is still renewed for the same amount of time as a standard approval.
  o The Determination Date and Approved From date will be the date of the IRB meeting
  o The Approved To date will be 364 days later

DOCUMENTATION OF THE REVIEW

HSERA
- An HSERA Comment should indicate which board is reviewing the protocol and on what date.
- During screening, Comments should be added to HSERA to provide the completed screening checklist signed by the administrator.
- During screening, Comments should be added to HSERA to provide any email correspondence related to the review and any documents related to the review received from the study team outside of HSERA.
- Assignment to PennERA from HSERA should occur as soon as the screening is complete and it is confirmed that the submission will not be returned for edits.
- During Pre-Meeting review, any email correspondence related to the review should be uploaded to HSERA comments and shared with the assigned reviewers and Board Chair.
UNIT 6 – CONVENED IRB REVIEW PROCEDURES
6.3 Convened Continuing Reviews

PAPER
- The checklist signed by the administrator should be printed and kept with the file
- During screening, any email correspondence related to the review and any documents related to the review received from the study team via email should be printed and kept with the file
- When the submission is ready to be scheduled, all documents submitted by the study team, any email correspondence received, and the final checklist should be compiled into a PDF portfolio to be sent to the members with the agenda
- During Pre-Meeting review, any email correspondence related to the review should shared with the assigned reviewers and Board Chair then printed and kept with the physical file.

PENN ERA

Summary Page- During letter drafting after the meeting the summary page should be updated to reflect:
- Updated Determination Date
- Updated Approved From Date
- Updated Approved To Date
Typically, there are no other revisions needed for the summary page. Any other changes should be discussed with the board Administrator first.

Agenda Notes General Review Page Data Entry –During Agenda Prep Be sure to fill in:
- Confirmation code
- Submit Date
- Accurate Review type (Review – Request for Continuation)
- Description field data entry should be completed with the agenda notes template provided in the Greater Than Minimal Risk CR Checklist:
  * Electronic Submission* or *Paper Submission*
  HSEREA Confirmation Code: (if paper remove this line)
  Enrollment Status:
  Note to the Reviewer:
  Study Purpose:
  The Following Documents Are Included:
  - HSEREA Continuing Review, confirmation code:, submitted
(a complete document list is always required including listing any documents or emails received during screening)

Letter Drafting Review Details Page Data Entry

During Agenda Prep fill in;
- Review Method (IRB Review)
- Review Category (Full)
- Board Name
- Agenda (YES)
- Agenda Date (Choose future agenda being built)
- Review meeting date (same as agenda date)
- Reviewer
- Determination (Must be PENDING for members to access)
- Determination date (Same as agenda date)

DO NOT UPDATE THE SUMMARY DURING AGENDA PREP.

After the meeting:
- Update Determination (Approved, Conditionally Re-Approved)
- Insert approval period (Date From, Date To)
UNIT 6 – CONVENED IRB REVIEW PROCEDURES
6.3 Convened Continuing Reviews

- Fill in Determination Comments with:
  - the complete document list from the Agenda (be sure to list any documents received from the study team after the agenda went to the members if any)
  - Any notes or stipulations that must appear in the letter
- Fill in Provisions with the finalized version of the Minutes approved by the IRB Administrator
- Fill in Votes
- Fill in Scientist/ Non-scientist fields.
- Draft

BE SURE TO UPDATE THE SUMMARY BEFORE DRAFTING THE LETTER

Draft one of the following letter templates:
- HS Continuing Review – Full
- HS Continuing Review – COND.
OVERVIEW
This procedure outlines the review of amendments that require convened review for ongoing projects that have already approved by the IRB and were submitted within the HS-ERA electronic submission system and paper submission process.

PROCEDURES
Screening-
Screening of Convened Modification submissions follows the procedures noted in GDO section 6.0 with the following clarifications:

After receipt of the assignment, the IRB Administrator conducts a preliminary screening by examining the HS-ERA application and all submitted documents to determine:

1. That the submission requires convened review due to the nature of the proposed changes in context of the research
2. That the assigned board has the appropriate expertise available to conduct the review
3. That the submission contains sufficient information for the Board to consider whether the study meets the criteria for approval in context of the proposed revisions and includes a summary of changes, rationale for the proposed revisions, and tracked/clean version of the revised documents. The requirements for modification submissions are clearly outlined in the Modification Submission form.

The IRB Administrator may utilize the Modification Standard Screening Checklist to prepare the submission for review however this is not required. To determine if the submission is ready for review, the IRB Administrator looks over the modification summary, tracked changes to the online application, and any attached documents. Once the above 3 determinations have been made and a basic review of the submitted documentation has been complete, the Administrator should determine course of action for any issues identified. IRB administrator may; return the submission for revision, email the study team for additional information/documentation, or place agenda notes for the board to consider whether stipulations or recommendations should be placed in the determination letter.

Depending on the nature of the changes, the IRB Administrator should also be aware of any additional worksheets that are required during full board preparations such as:

- Subpart B Worksheet (Research involving Pregnancy/ Fetuses/Neonates)
- Subpart C Worksheet (Research Involving Prisoners)
- Subpart D Worksheet (Research Involving Children)
- Drugs/Biologics Worksheet
- Devices Worksheet
- Department of Defense Checklist
- Department of Energy Checklist
- Department of Education Checklist
- Department of Justice Checklist
- Environmental Protection Agency Checklist

Once the submission is determined to be ready for convened review, the IRB administrator should prepare the Agenda notes for PennERA. Agenda notes for Convened modifications should align with the following:

*Electronic Submission* OR *Paper Submission*
Confirmation Code:
Protocol Description:
Modification Summary (As Provided by Submitter):
Reason For Convened Review:
Enrollment Status/Re-Consent Plan
The following Documents were included with this review:
(a complete document list is always required)

**Scheduling & Member Assignment**
Scheduling of Convened Modification submissions follows the procedures noted in GDO section 6.0 with the following clarifications:

- Modification reviews typically only have one reviewer unless the research or amendment is particularly complex
- Modifications are scheduled to be reviewed on the next agenda by the board with the appropriate expertise and agenda volume permits addition of another review.

**Convened Meeting Review**
Convened Meeting Review of Convened Modification submissions follows the procedures noted in GDO section 6.0 with the following clarifications For Initial Reviews:

The primary reviewer presents their findings to the convened IRB based on their review of the modification request. The Board discusses any issues with the submission raised by the primary reviewer as well as any potential issues or questions that may be raised by other members of the Board. The convened IRB considers the findings presented and makes a determination for approval, withheld approval, tabling, or disapproval of the modification. The Board may also re-assess the risk level of the study during a modification.

**Post Meeting Wrap up**
Post meeting wrap up follows the procedures outlined in the Convened Assignment Workflow GDO section 6.0

**GUIDANCE**

- IRB Administrators are tasked with preparation of modifications for full board review however Coordinators are typically required to perform all meeting wrap up. Generally, once the submission is ready and has been assigned to the agenda in PennERA, the HSERA assignment is transferred to the Coordinator to manage from their queue and complete any submission returns based on determination after the meeting.

- The outcome of modification reviews do NOT affect the Determination, Approved From or Approved To dates for a study so they should not be revised.

**DOCUMENTATION OF THE REVIEW**

**HSERA**
- An HSERA Comment should indicate which board is reviewing the protocol and on what date
- During screening, Comments should be added to HSERA to provide the completed agenda notes and any required checklists/worksheets completed by the administrator
- During screening, Comments should be added to HSERA to provide any email correspondence related to the review and any documents related to the review received from the study team outside of HSERA
- Assignment to PennERA from HSERA should occur as soon it is confirmed that the submission will not be returned for edits.
- During Pre- Meeting review, any email correspondence related to the review should be uploaded to HSERA comments and shared with the assigned reviewers and Board Chair

**PAPER**
- Any Checklists completed by the administrator should be printed and kept with the file
UNIT 6 – CONVENED IRB REVIEW PROCEDURES

6.4 Convened Modifications

- During screening, any email correspondence related to the review and any documents related to the review received from the study team via email should be printed and kept with the file.
- When the submission is ready to be scheduled, all documents submitted by the study team, any email correspondence received, and any required checklists should be compiled into a PDF portfolio to be sent to the members with the agenda.
- During Pre-Meeting review, any email correspondence related to the review should be shared with the assigned reviewers and Board Chair then printed and kept with the physical file.

PENN ERA

Summary Page- unless the modification includes administrative changes (e.g. title, PI, Sponsor) the Summary page should not be revised before, during, or after convened review of a modification. Any revisions to the summary page should be discussed with the Administrator first.

Agenda Notes General Review Page Data Entry – Be sure to fill in:
- Confirmation code
- Submit Date
- Accurate Review type (Amend-Amendment or Modification)
- Description field data entry should be completed with the agenda notes template provided above

Letter Drafting Review Details Page Data Entry- Be sure to fill in and VERIFY:

During Agenda Prep fill in;
- Review Method (IRB Review)
- Review Category (Full)
- Board Name
- Agenda (YES)
- Agenda Date (Choose future agenda being built)
- Review meeting date (same as agenda date)
- Reviewer
- Determination (Must be PENDING for members to access)
- Determination date (Same as agenda date)

After the meeting:
- Update Determination (Approved, Withheld Approval, Tabled, Disapproved)
- Fill in Determination Comments with:
  - the complete document list from the Agenda (be sure to list any documents received from the study team after the agenda went to the members if any)
  - Any notes or stipulations that must appear in the letter
- Fill in Provisions with the finalized version of the Minutes approved by the IRB Administrator
- Fill in Votes
- Fill in Physician / Non-scientist fields

Draft one of the following letter templates:
- HS Amendment – Full
- HS Amendment – Conditional
- HS Tabled
- HS Amendment- Disapproved
OVERVIEW
This procedure outlines the review processes for reports of protocol deviations submitted to the IRB via the paper and electronic submission processes which are found to require convened review.

PROCEDURES

Screening, Scheduling, Member Assignment:
Deviations referred for full board review follow slightly different procedures than what is outlined in section 6.0. All deviations are first screened via the expedited assignment workflow outlined in section 5.0. If the expedited review determines that the deviation may be accepted via expedited review, then the letter drafted during the expedited review process will end the review procedures for that action. However, if the expedited review results in a referral to the convened board review, the expedited letter will serve to acknowledged timely receipt of the report and inform the study team that Convened review for assessment of Noncompliance (including Serious or Continuing noncompliance) is required.

After the expedited screening and letter drafting, the convened review is scheduled in Penn ERA as soon as possible by a board with appropriate expertise to assess the deviation in context of the research design. The assigned reviewer (typically the Board Chair) may have additional questions for the study team that require response prior to the convened review. The IRB Administrator for the board conducting the convened review will work closely with the IRB Chair and the study team to obtain any necessary clarifications or documents.

Convened Meeting Review

Review of Deviations by the convened board are limited to determining whether the proposed corrective action plan is appropriate and whether the deviation qualifies as Non-compliance (including Serious or Continuing Non-Compliance). The definitions for these determinations are outlined in the Deviation & Reportable Event Checklist that should be filled out by the IRB administrator during the expedited review process. The Board should review and consider the report in context of these definitions.

Post Meeting Wrap up

Post meeting wrap up follows the procedures outlined in the Convened Assignment Workflow GDO section 6.0 and are usually conducted by the IRB Administrator unless delegated to a Coordinator with appropriate training.

GUIDANCE

A deviation reviewed by the convened Board may result in the following determinations:
- Accepted
- Accepted pending responses

A separate determination regarding the noncompliance is required. Noncompliance determinations may result in:
- Finding that the reported deviation is Not noncompliance
- Finding of Serious Non-Compliance
- Finding of Continuing Non-compliance
- Finding of Serious and Continuing Non-compliance.

The minutes for this discussion should be explicit and detailed regarding these separate determinations as well as rationale for each determination finding.

IRB Determination letters for convened Deviations should include:
UNIT 6 – CONVENED IRB REVIEW PROCEDURES

6.5 Convened Deviations

- clear language informing the study team of the determination that was made (even if the finding is not noncompliance),
- the definitions of noncompliance that were considered or found, and;
- indication of whether the deviation will be reported internally or externally based on the findings

Agenda notes for Convened Deviations should align with the following outline:

*Electronic Submission*

Confirmation code:
Deviation Summary
Root Cause
Corrective Action Plan

The following documents were included with the review:

- HSERA Deviation Report, confirmation code:, submitted

(a complete document list is always required and should be supplemented by any documents or emails received during screening and full board preparation)

There is no letter template for generating the specifics needed for a Convened Deviation Review letter. Administrators should generate a letter using the Amendment -Full template and make necessary revisions to the template. Using the PennERA comments to insert specific notes as well as making revisions to the template itself in a word document are generally required to draft a complete and appropriate Deviation Determination Letter.

DOCUMENTATION OF THE REVIEW

HSERA

- An HSERA Comment should indicate which board is reviewing the protocol and on what date
- During screening, Comments should be added to HSERA to provide the completed screening worksheet(s)
- During screening, Comments should be added to HSERA to provide any email correspondence related to the review and any documents related to the review received from the study team outside of HSERA
- Assignment in pennERA will be a secondary review created within the original expedited review.
- During Pre- Meeting review, any email correspondence related to the review should be uploaded to HSERA comments and shared with the assigned reviewers and Board Chair

PAPER

- Any checklists completed by the administrator should be printed and kept with the file
- During screening, any email correspondence related to the review and any documents related to the review received from the study team via email should be printed and kept with the file
- When the submission is ready to be scheduled, all documents submitted by the study team, any email correspondence received, and the final checklist should be compiled into a PDF portfolio to be sent to the members with the agenda
- During Pre- Meeting review, any email correspondence related to the review should shared with the assigned reviewers and Board Chair then printed and kept with the physical file.

PENN ERA
UNIT 6 – CONVENED IRB REVIEW PROCEDURES

6.5 Convened Deviations

Summary Page- Review of Deviations should not affect any information on the summary page. Any revisions to the summary page should be discussed with Senior Admins or Regulatory Reps

Agenda Notes General Review Page Data Entry – Be sure to fill in:
- Confirmation code
- Submit Date
- Accurate Review type (Deviation)

- Description field data entry should be completed and align with the outline shown above

- The reviews ribbon on the General Review page will need to have 2 reviews, one for the expedited review and one for the full/convened review. Once the full review is scheduled the radial button associated with the full review should remain selected

Letter Drafting Review Details Page Data Entry:

During Agenda Prep fill in;
Review Method (IRB Review)
Review Category (Full)
Board Name
Agenda (YES)
Agenda Date (Choose future agenda being built)
Review meeting date (same as agenda date)
Reviewer
Determination (Must be PENDING for members to access)
Determination date (Same as agenda date)

After the meeting:
Update Determination (Accepted, Accepted pending Responses)
Fill in Determination Comments with:
- the complete document list from the Agenda (be sure to list any documents received from the study team after the agenda went to the members if any)
- Any notes or stipulations that must appear in the letter

Fill in Provisions with the finalized version of the Minutes approved by the IRB Administrator
Fill in Votes
Fill in Scientist/ Non-scientist fields.
OVERVIEW
This section provides procedures and guidance for Exception Requests that require Convened Review.

PROCEDURES
Screening-
Screening of Convened Exception Requests submissions follows the procedures noted in GDO section 6.0 with the following clarifications:

Exception requests are generally assigned to Senior Analyst staff for assessment in collaboration with IRB Chairs and Directors.

There is no formal checklist required for assessment of exception requests. If an exception request is found to be complete according to the requirements outlined in the Exception Request form, it may be scheduled for convened review.

Scheduling & Member Assignment-
Scheduling of Convened Exceptions submissions follows the procedures noted in GDO section 6.0.

Convened Meeting Review
Convened Meeting Review of Convened Exceptions submissions follows the procedures noted in GDO section 6.0 with the following clarifications:

When an exception request is not time sensitive, the Convened IRB will be asked to review exception requests that may pose greater than minimal risk to the subject to determine:
- Whether the exception is in the best interest of the subject or whether there is a prospect for direct benefit to the subject
- Whether the risk to benefit ratio is favorable for the subject

Convened review of exception requests may result in either Approval or Disapproval determinations. The determination granted for the exception is generally approval for one subject only unless the exception is requested to apply to more than one subject.

Post Meeting Wrap up
Post meeting wrap up follows the procedures outlined in the Convened Assignment Workflow GDO section 6.0.

GUIDANCE
Convened review of exception requests are not common compared to other types of convened reviews.

Agenda notes for exceptions should align with the following outline:

*Electronic Submission* OR *Paper Submission*
Confirmation code:
Exception Description (as provided by the submitter):
This exception will not pose an additional risk to subjects for the reason indicated:
This exception is in the best interest of the subject due to the following:
The data obtained from the subject will not be compromised:
Enrollment Status:
Reason for Convened Review:
UNIT 6 – CONVENED IRB REVIEW PROCEDURES

6.6 Convened Exception Requests

The following Documents were included with the review:
- HSERA Exception Request, Confirmation code; Submitted

(a complete document list is always required)

HSERA
- An HSERA Comment should indicate which board is reviewing the protocol and on what date
- During screening, Comments should be added to HSERA to provide the completed screening worksheet(s)
- During screening, Comments should be added to HSERA to provide any email correspondence related to the review and any documents related to the review received from the study team outside of HSERA
- During Pre- Meeting review, any email correspondence related to the review should be uploaded to HSERA comments and shared with the assigned reviewers and Board Chair

PAPER
- Any checklists completed by the administrator should be printed and kept with the file
- During screening, any email correspondence related to the review and any documents related to the review received from the study team via email should be printed and kept with the file
- When the submission is ready to be scheduled, all documents submitted by the study team, any email correspondence received, and the final checklist should be compiled into a PDF portfolio to be sent to the members with the agenda
- During Pre- Meeting review, any email correspondence related to the review should be shared with the assigned reviewers and Board Chair then printed and kept with the physical file.

PENN ERA

Summary Page- Review of Exceptions should not affect any information on the summary page. Any revisions to the summary page should be discussed with Senior Admins or Regulatory Reps

Agenda Notes General Review Page Data Entry – Be sure to fill in:
- Confirmation code
- Submit Date
- Accurate Review type (Exception)
- Description field data entry should be completed and align with the outline shown above

  - The reviews ribbon on the General Review page will need to have 2 reviews, one for the expedited review and one for the full/convened review. Once the full review is scheduled the radial button associated with the full review should remain selected

Letter Drafting Review Details Page Data Entry-

During Agenda Prep fill in;
Review Method (IRB Review)
Review Category (Full)
Board Name
Agenda (YES)
Agenda Date (Choose future agenda being built)
Review meeting date (same as agenda date)
UNIT 6 – CONVENED IRB REVIEW PROCEDURES
6.6 Convened Exception Requests

Reviewer
Determination (Must be PENDING for members to access)
Determination date (Same as agenda date)

After the meeting:
Update Determination (Accepted, Accepted pending Responses)
Fill in Determination Comments with:
- the complete document list from the Agenda (be sure to list any documents received from the study team after the agenda went to the members if any)
- Any notes or stipulations that must appear in the letter
Fill in Provisions with the finalized version of the Minutes approved by the IRB Administrator
Fill in Votes
Fill in Scientist/ Non-scientist fields.

Please draft an HS Amendment-Full letter and make any necessary revisions to reflect approval of an Exception request.
OVERVIEW
This section outlines procedures and guidance for Reportable Adverse Event submissions which require convened Review.

PROCEDURES

Screening, Scheduling, Member Assignment:
Reportable Events referred for full board review follow slightly different procedures than what is outlined in section 6.0. All events are first screened via the expedited assignment workflow outlined in section 5.0. If the expedited review determines that the event may be acknowledged via expedited review, then the letter drafted during the expedited review process will end the review procedures for that action. However, if the expedited review results in a referral to the convened board, the expedited letter will serve to acknowledged timely receipt of the report and inform the study team that Convened review is required and if available the date of convened review.

After the expedited screening and letter drafting, the convened review is scheduled in Penn ERA as soon as possible by a board with appropriate expertise to assess the event in context of the research design. The assigned reviewer (typically the Board Chair) may have additional questions for the study team that require response prior to the convened review. The IRB Administrator for the board conducting the convened review will work closely with the IRB Chair and the study team to obtain any necessary clarifications or documents. The submission should not be returned in HSERA as this will cause technical errors.

Convened Meeting Review

Review of adverse events by the convened board should be focused on:
- Whether the report may be accepted or requires additional information for assessment
- Whether additional action in response to the event is needed
- Whether the reported event meets the criteria of an Unanticipated Problem Involving Risks to Subjects or Others. The definitions required for this assessment are outlined in the Reportable Event checklist that should be filled out by the IRB Administrator during the expedited review procedure.
- The Board may also need to make determinations of noncompliance depending on the circumstances of the reported event.

The outcome of convened review will result in either Accepted or Accepted Pending Responses.

The minutes discussion should explicitly describe each consideration and the results of each individual determination.

Post Meeting Wrap up

Post meeting wrap up follows the procedures outlined in the Convened Assignment Workflow GDO section 6.0 and are usually conducted by the IRB Administrator unless delegated to a Coordinator with appropriate training.

GUIDANCE
Agenda notes for Convened Reportable Events should align with the following outline:

*Electronic Submission*
Confirmation code:
Adverse Event Summary:
The following documents were included with the review:
- HSERA Deviation Report, confirmation code:, submitted
UNIT 6 – CONVENED IRB REVIEW PROCEDURES
6.7 Convened Reportable Events

(a complete document list is always required and should be supplemented by any documents or emails received during screening and full board preparation)

There is no letter template for generating the specifics needed for a Convened Deviation Review letter. Administrators should generate a letter using the Amendment -Full template and make necessary revisions to the template. Using the PennERA comments to insert specific notes as well as making revisions to the template itself in a word document are generally required to draft a complete and appropriate Deviation Determination Letter

DOCUMENTATION OF THE REVIEW

HSERA
- An HSERA Comment should indicate which board is reviewing the protocol and on what date
- During screening, Comments should be added to HSERA to provide the completed screening worksheet(s)
- During screening, Comments should be added to HSERA to provide any email correspondence related to the review and any documents related to the review received from the study team outside of HSERA
- Assignment in pennERA will be a secondary review created within the original expedited review.
- During Pre-Meeting review, any email correspondence related to the review should be uploaded to HSERA comments and shared with the assigned reviewers and Board Chair

PAPER
- Any checklists completed by the administrator should be printed and kept with the file
- During screening, any email correspondence related to the review and any documents related to the review received from the study team via email should be printed and kept with the file
- When the submission is ready to be scheduled, all documents submitted by the study team, any email correspondence received, and the final checklist should be compiled into a PDF portfolio to be sent to the members with the agenda
- During Pre-Meeting review, any email correspondence related to the review should be shared with the assigned reviewers and Board Chair then printed and kept with the physical file.

PENN ERA

Summary Page- Review of Adverse Events should not affect any information on the summary page. Any revisions to the summary page should be discussed with Senior Admins or Regulatory Reps

Agenda Notes General Review Page Data Entry – Be sure to fill in:
- Confirmation code
- Submit Date
- Accurate Review type (AE- Serious or Unanticipated Adverse Events)
- Description field data entry should be completed and align with the outline shown above
  - The reviews ribbon on the General Review page will need to have 2 reviews, one for the expedited review and one for the full/convened review. Once the full review is scheduled the radial button associated with the full review should remain selected

Letter Drafting Review Details Page Data Entry-
UNIT 6 – CONVENED IRB REVIEW PROCEDURES

6.7 Convened Reportable Events

**During Agenda Prep fill in;**

- Review Method (IRB Review)
- Review Category (Full)
- Board Name
- Agenda (YES)
- Agenda Date (Choose future agenda being built)
- Review meeting date (same as agenda date)
- Reviewer
- Determination (Must be PENDING for members to access)
- Determination date (Same as agenda date)

**After the meeting:**

- Update Determination (Accepted, Accepted pending Responses)
- Fill in Determination Comments with:
  - the complete document list from the Agenda (be sure to list any documents received from the study team after the agenda went to the members if any)
  - Any notes or stipulations that must appear in the letter
- Fill in Provisions with the finalized version of the Minutes approved by the IRB Administrator
- Fill in Votes
- Fill in Scientist/ Non-scientist fields.
OVERVIEW
The IRB supports the conduct of research designed for community level involvement and will generally be aligned with a request for exception from informed consent (EFIC). The IRB provides guidance to the researcher and their team related to these types of submissions by providing a timeline for best practices to have this research reviewed and providing support to the community consultation process. This section provides a brief overview of this program.

PROCEDURES
All procedures will follow the Convened Assignment Workflow outlined in section 6.0 as well as Convened Initial Review in section 6.2 additional guidance is provided below.

GUIDANCE
The initial review of research of this nature is focused solely on the plan for community consultation and outreach.

One of the IRBs at Penn has received specific training in EFIC research and community consultation and outreach. This IRB will review all requests for EFIC research and will attempt to maintain a membership that has at least one member who has an invested effort in the Philadelphia community or prior experience with research of this nature. Each IRB will always have a community member on the roster, but the community member may not be present at all meetings.

The specific training received by the IRB was led by the Program Manager for a researcher who has conducted EFIC research in the past. The Committee was informed of the expectations for their review of the community consultation and outreach plan and was encouraged to attend the scheduled sessions themselves.

If the pre-determined date of the meeting for the Committee did not allow for appropriate representation available for the meeting, the IRB may seek consult related to the community consultation plan or any other outreach procedures. The consultant would either attend the meeting for the review of the particular protocol or would provide commentary that would be provided to the members in advance of the meeting.

To date, there have been only a small number of requests for EFIC research; therefore, the application materials do not distinctly speak to the criteria necessary for exception from informed consent and the corresponding community outreach process. IRB staff will assist the researcher and their team with these types of submissions and will verify that enough information is present to determine that the community outreach plan is sufficient and will target the appropriate potential subjects. If any revisions are required to the community outreach plan, the IRB will raise these in the stipulations letter to the research and their team.

Once the community consultation plan is complete, the IRB will receive a report of the outcome and any revisions proposed to the initial research idea and/or design as warranted. The IRB will also be informed of approval, if required, or status of review, from any local offices or officials (i.e. City of Philadelphia representatives).

The Assistant Director provides initial support to the researcher and their team regarding creation of the IRB application and providing of the necessary components to consider the exception from informed consent and the corresponding community outreach plan.

The IRB Administrator schedules the submission for convened review and works with the members in advance of the meeting to address any substantial concerns. The IRB Administrator reports to the Assistant Director the attendance for the meeting that is reviewing the submission and verifies that the appropriate representation of the community will be present. If not, the IRB Administrator works with the Assistant Director to obtain a consult from an appropriate member/research community representative in advance of the meeting.

The IRB Administrator drafts the correspondence back to the researcher and their team outlining any stipulations and/or recommendations related to the community consultation plan. The IRB Administrator also receives the final report from
UNIT 6 – CONVENED IRB REVIEW PROCEDURES
6.8 Community Based Research / Exception From Informed Consent (EFIC)
the research and their team related to the outcome of community consultation and schedules this for review when complete.

Once the community consultation plan is accepted and the local reviews are completed as required, the remainder of the IRB review aligns with the standard practices for initial reviews (establishing the approval criteria are met and verifying that the research qualifies for exception from informed consent).

DOCUMENTATION OF THE REVIEW
Documentation of these reviews will generally align with documentation for any other research that requires convened review.
OVERVIEW

This section outlines procedures and guidance for responses to stipulations raised by the convened IRB. This section applies to responses that require convened review for Initial, Modification, Continuing Review. The majority of applications will be processed through HSERA, however information about paper responses is also provided. Convened responses to convened review follow the convened assignment workflow outlined in GDO section 6.0

DETERMINING WHEN A RESPONSE REQUIRES CONVENED REVIEW

Convened review is required for responses under the following circumstances:

- **Tabled or Disapproved Determination**: if the original convened review of an Initial or Modification submission results in a tabled or disapproved decision, the response automatically requires convened review. A tabled /disapproved determination is generally applied when there is a significant lack of information that prevents the board from deciding the criteria for approval are met OR if the issues raised cannot be communicated as a directive (i.e. the board has major questions and the answers to those questions cannot be readily estimated and will require further discussion).

- **Withheld Approval Determination with missing or new information**: if the original convened review of an initial or modification submission results in a withheld approval determination, the response will require convened review if the response does not fully address the board’s stipulations or if the response contains new substantial information that requires convened review.

- **Suspension or Termination**: if the original convened review of a continuing review results in the study being suspended or terminated, any responses received for those determinations will require convened review.

PROCEDURES

**Screening**

Screening of responses that require convened review follows the procedures noted in GDO section 6.0 with the following clarifications:

Upon receipt of a response, a screening is conducted by examining the HS-ERA application and all submitted documents to determine:

- That the response requires convened review
- That all stipulations raised have been addressed
- That the submission contains sufficient information for the board to consider whether the study meets the criteria for approval

**Specifically, for response to Initial review:**

1. *The IRB Administrator is tasked with assessing whether corporate contract approval is necessary, has been received or is still pending. The status of the contract should be consistently communicated in all IRB determination letters until after the contract has been approved and reviewed. Procedures for contract review are described elsewhere in the GDO.*

2. *The Administrator must assess all stipulations regarding ancillary review and determine whether those reviews have taken place, their outcome, or whether they are still pending. Requirement for ancillary review should be consistently communicated in all IRB determination letters until completion and satisfaction of any ancillary requirements. Please see the admin stip appendix for information regarding these stipulations.*

Thorough screening of responses must include assessment of the online application and all submitted documents in context of the original review minutes and the determination letter with stipulations. Response submissions must include a summary from the study team directly addressing each stipulation. All revised documents must include tracked changes to demonstrate the updates.
During the screening process, the Response to Stipulations checklist or another summary document should be drafted. Regardless of what document is utilized the following should be compiled and available for the board:

- An outline of the stipulations raised by the Board in the order they appear in the determination letter
- Below each stipulation, a summary of the response provided by the study team and any comments that should be brought to the convened board’s attention.
- The summary document should also include the minutes from the Board’s first review of the submission.
- Based on the revisions being made, additional worksheets or checklists may be required (Drugs, Devices, Subparts etc…)

**Scheduling, Member Assignment and Pre-meeting Review**

Scheduling of responses that require convened review follow the procedures noted in GDO section 6.0 with the following clarifications:

- The response should be assigned to the board member who was the primary reviewer of the original submission if available, otherwise it should be assigned to the board Chair

**Convened Review**

Convened Meeting Review of responses that require convened review follow the procedures noted in GDO section 6.0 with the following clarifications:

- Prior to the general discussion of the response submission and primary reviewer presentation of their findings, the board should be presented with an overview of the original review (or reviews) discussion and a summary of the substantial issues that were raised.
- Convened review of responses to Initial review may result in:
  - Another tabled decision
  - Another withheld approval decision
  - Full approval
- Convened review of responses to modifications may result in:
  - Another tabled decision
  - Another withheld approval decision
  - Full approval
- Convened review of responses to continuing review may result in:
  - Continued suspension or termination
  - Conditional -re approval
  - Full approval

**Post Meeting Wrap up**

Post meeting wrap up follows the procedures outlined in the Convened Assignment Workflow GDO section 6.0 with the following clarifications:

- Documenting the approval of documents across responses is the responsibility of the screener and requires multiple lists identifying approval of documents according to the confirmation code or date of submission with
which they are approved. The Response to Stipulations checklist is set up to include 2 lists (one to list documents that were “approvable” with the original submission and one list to capture approval of revised and new documents submitted with the first response). Depending on how many times a submission is reviewed and returned, more separate lists may be required.

- The topmost document list should be the only list which includes the HSERA Application since all previous applications were returned they cannot be considered approved.
- Documents should only be listed ONCE. An individual document should not appear in multiple lists. For example, the document listing shown below is incorrect because it names the consent form in both lists. Since the consent form was the document related to the only stipulation for this review, the version reviewed on 12/19/2018 is NOT approved. Only the version submitted with the response is approved. Thus, the consent form included with the response should be listed and the consent forms mentioned from the original submission should be removed from the list:

```plaintext
The following documents were included in the response:
- HSERA Response Submission, confirmation code: xxxxxx, submitted on 01/15/2019
- Response Cover Letter, dated 1/15/2019
- Consent Form tracked changes version 14Nov2018
- Consent form Clean version 14Nov2018

The following documents submitted under code: (xxxxxxx), were previously reviewed by the IRB on 12/19/2018 and are now approved:
- IRB Modification Form [Modification Form_03Dec2018]
- Cover letter dated 12/3/18
- Patient brochure [Brochure102_V2_CountryCode_Language_FormattedTemplate]
- Patient emergency card track change [PatientEmergency_CountryCode_Language_V3_TrackChange]
- Patient emergency card clean [PatientEmergencyCard_V3_CountryCode_Language_FormattedTemplate]
- New protocol [SYNT001-102_Protocol Amendment 5_Final_23Oct2018]
- New protocol summary of changes [SYNT001-102_Protocol Amendment 5_Final_23Oct2018_SOC]
- New protocol track changes [SYNT001-102_Protocol Amendment 5_Final_23Oct2018_TC]
- Consent form tracked changes [SYNT102_107_14Nov2018]
- Consent form clean [SYNT102_107_14Nov2018_jw_clean]
```

**DOCUMENTATION OF THE REVIEW**

**HSERA**

- An HSERA Comment should indicate which board is reviewing the submission and on what date.
- During screening, Comments should be added to HSERA to provide any screening worksheet(s).
- During screening, Comments should be added to HSERA to provide any email correspondence related to the review and any documents related to the review received from the study team outside of HSERA.
- During Pre-Meeting review, any email correspondence related to the review should be uploaded to HSERA comments and shared with the assigned reviewers and Board Chair.

**PAPER**

- Paper response submissions are only expected for continuing reviews and modifications related to studies that pre-date the HSERA system and are documented in a study file. For paper studies, any documents or emails that would be added to the comments section of HSERA should be shared via email with the board members and chair and printed for the study file.
Summary Page-
For response to Initial: Depending on the outcome, summary page updates will likely be required to reflect the new determination and determination dates.

For response to Modification: Regardless of the outcome, Summary page updates will not be required to reflect determination or determination dates. If any administrative info regarding the study has been revised with the modification, those changes should be made by the IRB administrator during screening.

For response to Continuing Review: Depending on the outcome, summary page updates will likely be required to reflect the new determination and determination dates.

Agenda Notes General Review Page Data Entry
Date entry on this page will follow the same standards as the original convened submission with the following exceptions:
- Review Type should be set as:
  - Response to Initial review
  - Response to Continuing Review
  - Response to Amendment
- The document list should be divided into sections as described in the guidance above.

Letter Drafting Review Details Page Data Entry-
Date entry on this page will follow the same standards as the original convened submission with the following exceptions
- The document list should be divided into sections as described in the guidance above.
UNIT 7
RESEARCH AGREEMENTS

7.1 Determining Engagement In Research

7.2 Individual Investigator Agreements

7.3 IRB Authorization Agreements - Penn As IRB of Record

7.4 IRB Authorization Agreements - Penn As Relying IRB

7.5 Penn/CHOP Cooperative Agreements

7.6 Research Conducted at Monell Chemical Senses Center

Back to Main Table of Contents
UNIT 7 – RESEARCH AGREEMENTS
7.1 Determining Engagement in Research

OVERVIEW
Penn investigators often participate in research studies that involve sites and groups outside of Penn. For multi-site studies where Penn is not serving as the central IRB of record for participating sites, each site is responsible for obtaining their own IRB approval.

When the Penn investigator is the lead investigator for a study or Penn is the lead site for a study, the Penn IRB may assist in determining which sites and outside groups involved are engaged in the research. The term “engaged in research” is defined according to the federal regulations and guidance provided by the Office of Human Research Protections and the FDA. All sites that are engaged in human subject research must obtain IRB approval of their activities. This section will outline the procedure for an administrator to determine if a site or individual is engaged in human subjects’ research.

PROCEDURES

While screening a submission, the IRB Administrator should make note of the entities outside of Penn that are participating in the research. The IRB Administrator should also note whether the Penn site and/or investigators are taking a lead role in the research. If Penn is taking a lead role in the project and there are other sites involved, the IRB Administrator should confirm whether the other sites are obtaining their own IRB approval for their engagement in the research. If this confirmation cannot be provided, the IRB Administrator should verify the roles of the other sites in the project and the specific activities the other sites will conduct. The IRB Administrator should request information to determine if the site’s personnel will consent subjects, collect data, or analyze identifiable information.

If the researchers indicate that personnel at the external site will do this, then the IRB Administrator should confirm that the site is engaged and that the site’s activity will need to be reviewed and approved by an IRB. The IRB Administrator should confirm that the site does or does not have an IRB that will review its role in the research. If the site does not have an IRB, the IRB Administrator considers whether the Penn IRB can enter into an Individual Investigator agreement with the associated research personnel can be executed. If the site does have an IRB, the IRB Administrator will discuss with the Director, or appropriate Senior Staff, if an Institutional Authorization Agreement with the site can be executed.

The IRB Administrator will assist the study team in moving through either process, if necessary. The study can be approved prior to receipt of IRB approval of finalized agreements with the other sites. However, the study team must confirm that no research will be conducted at those sites before IRB approval of any applicable agreement(s) is in place.

If the site is determined to not be engaged in research, then the IRB Administrator can relay this information to the researchers and note that no further action is necessary.

This process often occurs during initial review of a protocol. However, it can also be completed as part of a modification review if the modification adds additional sites to the protocol.
OVERVIEW
The IRB may be asked to serve as the IRB of record for independent investigators who are affiliated with an institution or office (e.g. a single physician in a private practice) that does not possess an FWA. Through the process of an Individual Investigator Agreement, the Penn IRB may extend the Penn Federalwide Assurance to cover this person’s involvement in research. This section details how the IRB reviews and approves these agreements when conducting a review.

PROCEDURES
Within an initial review or within a modification application, the IRB Administrator may receive a request for Penn to extend its purview over an unaffiliated individual. A collaborating independent investigator is defined as a person who is not otherwise an employee or agent of an institution with an IRB; conducting collaborative research activities outside the facilities of the institution; and not acting as an employee of any institution with respect to his or her involvement in the research being conducted by the institution.

The IRB Administrator should identify that the investigator(s) is unaffiliated with another IRB. The IRB Administrator should also obtain details of the individual’s role in the research and documentation that the individual has completed human subjects’ research training. If the preliminary review of the request is found to be appropriate, the IRB Administrator requests a copy of the Individual Investigator Agreement document signed by the unaffiliated investigator. The signed agreement is then forwarded to the Penn IRB Director for review and signature approval.

The IRB Director reviews the submission and determines if the agreement is appropriate. If the Director approves the request, the Director signs the agreement and forwards this letter to the Assistant or Administrator processing the request.

DOCUMENTATION OF THE REVIEW

HSERA
- Any investigator active on a Penn research protocol that enters into an IIA should be identified by name and role in the Resources Necessary section of HSERA
- The IIA signed by both parties (the investigator and the IRB director) should be attached to the HSERA

Comments
- Documentation of CITI training for the investigator should be provided

PAPER
- Any investigator active on a Penn research protocol that enters into an IIA should be identified by name and role in the protocol
- The IIA signed by both parties (the investigator and the IRB director) should be printed and stored with the study file

PENN ERA

IIA’s should be identified on the Summary page of PennERA in the Overview section or the Name Of Institutions Comments section
OVERVIEW
The Penn IRB may be asked to serve as the IRB of record for one or more external sites or a multi-site study. Similarly, the Penn IRB may be asked to serve as the central IRB for all active sites in a research study. This section describes procedures and guidance for engaging in these types of agreements.

IRB Authorization agreements may be requested because:
- The requesting institution may not have its own IRB
- The research may be a multi-site protocol where single IRB review is required by the Common Rule or by NIH funding policies

PROCEDURES
Procedures for studies with a reliance agreement will generally follow the Expedited or Convened workflow procedures outlined in sections 5.0 and 6.0 with the following clarifications:

Modification – Penn is the IRB of Record – Site Addition Mod
1. Open the submission in HS-ERA
2. Complete the Site Addition Mod Screening Worksheet
3. Attach the completed worksheet to the HS-ERA submission and assign the action to an IRB – Feed into PennERA
4. Here is a comment you can use when attaching the worksheet: Request to add a relying site. Please see the attached worksheet.
5. Open the protocol in PennERA and update summary page record’s data entry
   a. Overview section should indicate this Penn is the IRB of Record for multiple study sites
   b. IRB Authorization Agreement – Penn IRB of Record box should be checked
   c. The Name of Institution(s)/Comments: section should include a bulleted list of all the relying sites
   d. Update this list to include the site that you are adding
6. Open the submission record in PennERA and complete the data entry
   a. Paste the confirmation code in the submission number field
   b. Assign PAS/TAZ/DH as the reviewer
   c. Change the determination from logged to pending
7. You are done. The action will be approved and should appear on tomorrow’s letter generation report.

Examples:
- 820147-Carey- chedbcfi: mod adding a relying site that did not require a site specific consent

Modification – Penn is the IRB of Record – Other Mods
Screen the modification as you would normally. Use the Mod Standard Screening Worksheet.

Additional Step 1: Determine if modification is site specific or protocol wide
- If site specific, check PennERA date entry to confirm that we are the IRB of Record for that site.
- If protocol wide, make sure we have any applicable revised documents for the relying sites (updated consent forms, recruitment materials, etc).

Additional Step 2: Check Data Entry on PennERA summary page
- Overview section should indicate that Penn is the IRB of Record for external sites (each site does not have to be named in this section)
- IRB authorization agreement – Penn IRB of Record box should be checked
- Name of Institution/Comments section should include a bulleted list of the sites relying on the Penn IRB.

Examples:
UNIT 7 – RESEARCH AGREEMENTS
7.3 IRB Authorization Agreements – Penn as IRB of Record

- 820678-Merkel-cheahedb: Mod where Penn is the IRB of Record for multiple site but required little additional work.
- 820147-Carey-chejghdh: Mod where Penn is the IRB of Record. Mod provides consent form for a relying site for stamping.

Continuing Review – Penn is the IRB of Record

Screen the CR as you would normally. Use the CR Standard GTMR/Minimal Screening Worksheet.

Additional Step 1: Review progress reports for the relying sites
- Check PennERA summary page for list of relying sites.
- Each relying site should be discussed in the progress report
- If they are using the CR supplement forms there should be a separate supplement for each relying site
- If they are enrolling subjects at the relying site, there should be a consent form for that relying site.

Additional Step 2: Check Data Entry on PennERA summary page
- Overview section should indicate that Penn is the IRB of Record for external sites (each site do not have to be named in this section)
- IRB authorization agreement – Penn IRB of Record box should be checked
- Name of Institution/Comments section should include a bulleted list of the sites relying on the Penn IRB.

Examples:
- 815495-Seligman-chedbfei: CR where Penn is the IRB of Record for another site but the site doesn’t enroll subjects.

GUIDANCE

- All IRB Staff and any investigators / research staff involved in the process of approval for Penn to serve as the IRB of record for one or more sites should be familiar with the guidance information posted on the IRB website https://irb.upenn.edu/reliance-agreements. The guidance documents posted there provide very specific step by step guidance for requesting, obtaining and maintaining approval of an IRB authorization agreement.

DOCUMENTATION OF THE REVIEW

HSERA
- Documentation of reviews in HSERA will follow the same documentation procedures as any other submission described throughout the GDO

PAPER
- Request for IRB Authorization agreements for paper studies is now very infrequent/rare. Paper Documentation procedures will align with the same paper documentation procedures as any other submission described throughout the GDO

PENN ERA
Summary Page- When Penn Serves as the IRB of record for other sites, a running list of all sites we review for should be compiled in the “Name of Institutions/Comments” box for that particular study. The UDF for “IRB Authorization Agreement - Penn IRB of Record” should always be checked.

Determination Letter – When penn serves as the IRB of record for other sites, a note should be included in the determination letter indicating that the site has been approved. Any finalized IRB authorization agreements should be attached to the relevant letter when being sent to the study team. Other PennERA documentation will depend on the type of submission at hand.

Guide to Daily Operations V. 10
UPENN IRB
OVERVIEW
The Penn IRB may be asked to rely on another IRB for research taking place at Penn. Usually this is because the research is a multi-site protocol where single IRB review is required by the Common Rule or by NIH funding policies.

PROCEDURES
The procedures for Reliance Agreements generally follow the procedures outlined in section 5.0 with the following clarifications:

Initial Review – Penn is the Relying IRB
Step 1: Assign to IRB
- Feed the action into PennERA
- Reliance agreements can be assigned to any IRB – SBS requests should be assigned to IRB 8, CTRC requests should be assigned to 3

Step 2: Complete the Reliance agreement Request Screening Worksheet
- Submission can be returned if there are documents missing, CITI is incomplete, or consent edits are required
- Note the CRU does not typically complete the protocol supplement. I’ve been able to complete screenings without this document but you can request it if you think it’s needed. I have told Christine Bonney that when other staff start screening these actions, they will probably be asked to start including this form.

Step 3: Complete the Data Entry
  1. Attach the completed worksheet to the HS-ERA submission and assign the action to an IRB – Feed into PennERA (if necessary)
     a. Here is a comment you can use when attaching the worksheet: Submission is a request to rely on an external IRB. Please see the attached worksheet.
     b. If there is an IRB authorization agreement or other doc TAZ should sign, please upload it to the comments section with a comment that requests TAZ signature.
  2. Open the protocol in PennERA and complete the summary page record’s data entry
     a. Review Category should be Reliance agreement
     b. Determination should be Pending
     c. Overview section should indicate this is a reliance agreement protocol
     d. IRB Authorization Agreement – External IRB of Record box should be checked
     e. The Name of Institution(s)/Comments: section should list the name of the IRB of Record
  3. If the original submission had been returned for revision, make sure the data entry for the first review is complete
     a. The confirmation code should be placed in the submission number field
     b. The submit date field should be correct
     c. The Review category on the post review page should be Reliance agreement
     d. Agenda should be No
     e. The determination should be issue identified
     f. The determination date should be the date the submission was returned
  4. Place the submission up for review:
     a. Open the submission record in PennERA and complete the data entry
     b. Paste the confirmation code in the submission number field
     c. On the post review page, the review category should be reliance agreement
     d. Assign PAS/TAZ/DH as the reviewer
     e. Change the determination from logged to pending
  5. You are done. The action will be approved and should appear on tomorrow’s letter generation report.

Examples:
UNIT 7 – RESEARCH AGREEMENTS
7.4 IRB Authorization Agreements – Penn as Relying IRB

- 831825-Rothstein-chehbcca: Reliance request that was returned for revision before being placed up for review.
- 831776-Brucker-chehcbdi: Reliance request that was eligible for Approved-Relying IRB at the time it was submitted.
- 831906-Mangan-chfbejbc: CRU reliance request

Modification – Penn is the Relying IRB

Step 1: Identify the Purpose of the Mod
- It is likely providing updated approval documents from the central IRB
- Are any changes being made to the online application?

Step 2: Determine if a screening worksheet needs to be completed
- If the study is in acknowledged status and the modification moves the study to Approved-Relying IRB status, then a worksheet is required.
- If there are Penn site administrative changes that need to be reviewed, then a worksheet is required. The following are changes that need to be reviewed by the Penn IRB
  - Addition of Penn Personnel
  - Changes to FCOI
  - Revisions to Penn template consent language (injury, COI disclosure)
- If there are no changes then, a worksheet is not required.
  - The modification could include a tracked consent or revised protocol. If those are all study wide changes that were reviewed by the relying IRB, no worksheet is required.
- If a worksheet is required, please follow Instruction Path A
- If no worksheet is required, please follow Instruction Path B

Instruction Path A – When a worksheet is required
6. Open the HS-ERA Submission
7. Open and Complete the Relying IRB MOD Screening Worksheet
8. Attach the completed worksheet to the HS-ERA submission and assign the action to an IRB – Feed into PennERA
   a. Here is a comment you can use when attaching the worksheet: Mod for study where Penn is the Relying IRB. Please see the attached worksheet.
9. Open the protocol in PennERA and check summary page record’s data entry
   a. Review Category should be Reliance agreement
   b. Overview section should indicate this is a reliance agreement protocol
   c. IRB Authorization Agreement – External IRB of Record box should be checked
   d. The Name of Institution(s)/Comments: section should list the name of the IRB of Record
10. If study status is changed to Approved Relying IRB or the expiration date is changing, update the PennERA Summary page to reflect the current approval period listed on the IRB of Record approval letter (this can be done even before the HS-ERA approval button is selected)
11. Open the submission record in PennERA and complete the data entry
   a. Paste the confirmation code in the submission number field
   b. On the post review page, the review category should be reliance agreement
   c. Assign PAS/TAZ/DH as the reviewer
   d. Change the determination from logged to pending
12. You are done. The action will be approved and should appear on tomorrow’s letter generation report.

Examples:
- 831321-Bryer-cheddggg: mod moving status from Acknowledged to Approved-Relying IRB
Instruction Path B – When no worksheet is required

1. Open the protocol record in PennERA
2. Open the central IRB of record approval letter attached to the HS-ERA submission
3. If necessary, update the PennERA summary page to reflect the current approval period listed on the IRB of record approval letter
   a. If the study is listed as expired in PennERA and you do not have a current approval letter, please email the study team to request the letter.
   b. Do not move forward until you have received a current approval letter
4. Check the PennERA summary page record’s data entry
   a. Review Category should be Reliance agreement
   b. Overview section should indicate this is a reliance agreement protocol
   c. IRB Authorization Agreement – External IRB of Record box should be checked
   d. The Name of Institution(s)/Comments: section should list the name of the IRB of Record
5. Assign the HS-ERA record to an IRB – feed action into PennERA
6. Email the study team an acknowledgment of the submission. Below is example text
   Hi Peggy,

   I just wanted to let you know that we received your modification to the UPCC 26417 study and updated our record to include this approval from the Western IRB. The HS-era confirmation code for this submission was: checfdgj. Please let me know if you have any questions. Thanks again!

7. After sending the email, convert it into a PDF
8. Attached PDF’d email to HS-ERA submission with the following comment: Submission provides updated approval docs from the central IRB. PennERA has been updated to reflect the current approval. Nothing further is required. Email acknowledgment sent to the study team.
9. Open the submission record in PennERA and complete the data entry
   a. Paste the confirmation code in the submission number field
   b. Make sure the description includes an appropriate description of the submission (no doc list required)
   c. On the post review page, the Agenda field should be No
   d. Assign yourself as the reviewer
   e. Change the determination from logged to acknowledged
   f. Set today as the determination date.
10. You are done. No review letter is required. The action will not appear on tomorrow’s letter report.

Examples:
- 827714-Vogl-checfdgj: provided updated approval and the protocol had a current expiration date.
- 826003-Clark-chdgeafe: CR submission that made no changes to the application

GUIDANCE

- All IRB Staff and any investigators/research staff involved in the process of approval for Penn to rely on another IRB should be familiar with the guidance information posted on the IRB website https://irb.upenn.edu/reliance-agreements. The guidance documents posted there provide very specific step by step guidance for requesting, obtaining and maintaining approval of a Penn Reliance agreement.
OVERVIEW
The Penn and CHOP IRB have entered into a cooperative agreement that establishes a streamlined process for studies where both institutions are engaged in the research. The process allows for one IRB to serve as the IRB of Record for both institutions. This section details how the IRB reviews protocols that request a Penn/CHOP cooperative agreement. Both Penn and CHOP both retain the ability to review certain modifications even after an agreement is place, if review by the home institution is necessary.

PROCEDURES
When Penn will serve as the IRB of Record
Requests for Penn to serve as the IRB of record for CHOP will follow the same submission and review procedures outlined in GDO units 5 and 6 depending on level of review required. The only clarification is the requirement for completion of a Penn Chop Cooperative agreement form. The Penn/CHOP agreement form should be included in the initial application and completed by the Principal Investigator indicating Penn will be the IRB of record. Upon receipt and agreement to serve as the IRB of Record, the Penn IRB Director will sign the agreement form. The signed form will be appended to the IRB Determination letter and requires signature from the CHOP IRB Director agreeing to defer IRB review to Penn. A list of CHOP personnel should also be provided. The finalized agreement should be submitted back to the PENN IRB. After the agreement is finalized, the IRB staff is tasked with forwarding all IRB Correspondence directly to the CHOP IRB agreements Inbox (irbcorr@email.chop.edu)

When CHOP will serve as the IRB of Record
Requests for CHOP to serve as the IRB of record are received through the Penn CHOP Agreements inbox managed by the Penn IRB Assistant Director. pennchop@exchange.upenn.edu. Upon receipt of documents to this inbox the Penn IRB will create or update administrative PennERA records for studies taking place at Penn where CHOP is the IRB of Record. This reduces burden on research staff submitting to CHOP and then also submitting to Penn via HSERA. All documents received through the inbox are screened and attached to the PennERA attachments. As the CHOP IRB conducts continuing review and modification submissions, the determination letters and any pertinent study documents are forwarded to the Penn CHOP Agreements inbox. The IRB assistant Director or designee will update PennERA accordingly based on the documentation provided.

Initial Review – CHOP is the IRB of Record
Step 1: Receipt of the Penn/CHOP determination request
- Request will come from the CHOP IRB via an email to pennchop@upenn.edu
- Email may be forwarded to an IRB Admin for screening
- After receiving the email you should print out the email and all the attachments.

Step 2: Create a protocol number
- Create the protocol number in HS-ERA. Here are some tips to remember
  - The CHOP IRB number should be listed in the protocol title
  - The Penn investigator should be listed as the PI. This can be found either on the determination form or in the email from the CHOP IRB
  - Make sure a sponsor has been assigned in PennERA
  - Make sure the CHOP IRB of Record UDF is checked on the summary page

Step 3: Screen the request
- Ready the determination form and the email to determine if they are enrolling subjects.
- If they are enrolling subjects, the consent should indicate that data will be shared with investigators at CHOP and Penn
- If they are not enrolling subjects, determine if Penn EMR data is being sent to CHOP for use in the analysis under a HIPAA waiver.
Step 4: Email the study team
- The Penn PI should be emailed to confirm the Penn study team members, whether there are any conflicts and to complete the PI assurance. They should also address any issues identified at screening. Here is an example email:

Good morning,

I am reviewing a request to put a Penn/CHOP Cooperative Review agreement in place for your study titled, “Risk factors and Malignancy Outcomes among Pediatric Solid Organ Transplant Recipients.” This request has been assigned Penn IRB Protocol Number 831971.

I have a couple questions for you about the request. I would appreciate it if you or another member of your team could respond to the following:

1. In addition to yourself, will any other Penn affiliated personnel be involved in this project? If yes, please provide me with their names.
2. Can you please confirm whether any Penn affiliated personnel have potential financial conflicts of interest related to this protocol that require a disclosure through the FIDES system?
3. Please complete the attached PI assurance addendum.

Thank you very much for your assistance. Please let me know if you have any questions.

- Here is an example request if the study involves a HIPAA waiver:
  The application indicates that data will be collected from Penn medical records and then transferred and stored at CHOP. Can you please confirm that you will code the Penn Data so that it is considered a limited dataset under HIPAA before it is sent to CHOP?

Step 5: Receive the response:
- Once the study team has provided the additional information you can move forward
- If additional staff have been identified, use HS-ERA to verify that CITI is current
- If conflicts have been identified, notify Dave and wait to see if this request can move forward.

Step 6: Put up for review
- Print out any email correspondence and add it to the other documents
- Put a note on the top page of the submission (NOT THE DETERMINATION FORM), detailing that your review is completed. Here is a suggested note: This is a request to rely on the CHOP IRB. The PI assurance has been signed and the study team addressed all my questions. I have no concerns with the request. Ready for approval.
- Place the packet on TAZ’s desk for signature.
- You are now down. Tracy will sign the request and a letter will be generated.

Modification – CHOP is the IRB of Record
The only modification’s we typically process are personnel mods. This will come in via email. The staff should be informed who to send these requests to when PAS is out of the office.

Step 1: Receive and screen the request
UNIT 7 – RESEARCH AGREEMENTS
7.5 Penn/CHOP Cooperative Agreements

- Identify the Penn IRB Protocol number if it was not provided in the email.
- If you have the CHOP Protocol number you can search PennERA by putting that number in the title field.
- Print out the request.
- Identify the Penn personnel being added and verify CITI training.

Step 2: Place request up for review
- Document your screening on the email provided. Here is a suggested note: CHOP Is the IRB of Record. This is a request to add Penn Personnel. CITI training was provided. I recommend approval.
- Please put the Penn IRB number at the top of the submission so that it can be easily identified.
- Place the submission on the signing table for review and approval.
- You are now done. The request will be signed and a letter will be generated.

Updated Letter – CHOP is the IRB of Record

Step 1: Receipt of the CHOP approval letter
- Request will come from the CHOP IRB via an email to pennchop@upenn.edu
- PAS and Emily have access to that inbox. Emily should be told where to forward these emails.
- If multiple attachments are included in the email, I recommend combining them into one PDF. The approval letter should be the first document in the combined PDF.

Step 2: Locate the Protocol
- The email from CHOP will probably have the Penn IRB approval number
- If it doesn’t have the approval number or the approval number is correct, you can typically find the study via a title search
  o The CHOP IRB number is usually included in the protocol title so you can search by that
  o Searching by title keywords is also helpful.
  o I don’t recommend searching by Penn PI name

Step 3: Update the Protocol Record
- Open the protocol in PennERA
- Check the data entry
  o Review Category should be Reliance Agreement
  o Determination should be Acknowledged CHOP-Penn
  o Approved From/To dates should be updated to be in line with the dates in the approval letter you received
  o The Overview section should say this is a Penn/CHOP protocol
  o The CHOP IRB of Record UDF should be checked

Step 4: Upload the document
- Go to the attachments section in PennERA
- Add the Approval letter
  o Change the category to External IRB Determination Letters
  o Name the document. Here’s an example: 2018-11-6 CHOP CR Approval

You are done. Close the protocol and move the original email from CHOP to your email archive

DOCUMENTATION OF THE REVIEW

Guide to Daily Operations V. 10
UPENN IRB
When Penn is the IRB of record documentation of the review will generally follow procedures outlined for specific submissions throughout the GDO with the following clarifications:

**HSERA**
- The finalized cooperative agreement form should be attached to the comments

**PAPER**
- The finalized cooperative agreement form should be printed and kept with the file

**PENN ERA**

**Summary Page**
When Penn Is IRB for CHOP – Determination should always be Approved CHOP Penn
When Chop Is IRB for Penn – Determination should always be Acknowledged CHOP Penn

The UDF for Penn CHOP Agreements on the summary page and the date of finalization should always be filled in.
OVERVIEW
Monell Chemical Senses Center is an independent institution that has entered into an agreement to rely on the Penn IRB to complete human subjects’ research reviews for Monell researchers. This section reviews the process for completing Monell Chemical Senses Center reviews.

PROCEDURES
Generally, the procedures for research conducted at Monell will follow the workflows outlined in sections 5.0 and 6.0 of the GDO depending on level of review required. Please refer to the appropriate actions above to process the current submission submitted by Monell.

GUIDANCE
There are some specific considerations for Monell applications:

- Not all Monell personnel are selectable within the Penn IRB review system. If those individuals are selectable, then the IRB Administrator should request that they be added to the HSERA application for any initial review. If the Monell personnel are not selectable within the Penn submission system, the Administrator should request a list of all Monell personnel that are not selectable and request their CITI human subjects training information.

- Monell applications typically contain a template consent form addendum for employees and family members that enroll in Monell research studies. This document has already been reviewed and approved by the IRB and so no further review other than documenting its inclusion is required. In addition, this consent form addendum does not require an IRB approval stamp.

- The Penn IRB and Monell have agreed upon template language regarding research related injury and the inclusion of research information in the medial record. The IRB Administrator should review the consent form to ensure that this template language is appropriately incorporated.

- Monell is not a HIPAA covered entity. Therefore, medically based studies conducted solely at Monell are not required to include a research HIPAA authorization. However, if Monell is interacting with the University Health System, the IRB Administrator should determine if a HIPAA authorization is required.
APPENDIX 1
DRUG RELATED DEFINITIONS AND BACKGROUND INFORMATION

Definitions
Investigational New Drug (IND)
An application to the FDA to investigate a new drug or an established drug in an investigational manner. Current Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because a sponsor will probably want to ship the investigational drug to clinical investigators in many states, it must seek an exemption from that legal requirement. The IND is the means through which the sponsor technically obtains this exemption from the FDA.

IND Exempt
An application to the FDA is not required.

Types of Drug Products

<table>
<thead>
<tr>
<th>Drug</th>
<th>“articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease…” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals.” FD&amp;C Act, Section 201(g)(1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biologic</td>
<td>“…a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.” This definition includes, among other products, bacterial vaccines, allergenic extracts, gene therapy products, growth factors, cytokines, and monoclonal antibodies. 42 USC 262(i)</td>
</tr>
<tr>
<td>Cold Isotope</td>
<td>Non-radioactive isotope of a drug. (Regulations based on criteria for radioactive drugs, 21 CFR 361.1)</td>
</tr>
<tr>
<td>Cosmetic</td>
<td>&quot;(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.” 21 USC 321(i)</td>
</tr>
<tr>
<td>Dietary Supplement</td>
<td>Product taken by mouth that is intended to supplement the diet and that contains one or more dietary ingredients. This includes vitamins, minerals, herbs, and other botanicals, amino acids, other dietary substances intended to supplement the diet, and concentrates, metabolites, constituents, extracts, or combinations of the preceding types of ingredients. DSHEA of 1994</td>
</tr>
<tr>
<td>Food</td>
<td>“(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” 21 USC 321(f). It is the responsibility of the manufacturer of any food to ensure that all ingredients used are of food-grade purity and comply with specifications and limitations in all applicable authorizations. The overall regulatory status of a food is affected by the regulatory status of each individual food ingredient.</td>
</tr>
<tr>
<td>Food Additive</td>
<td>Any substance that is reasonably expected to become a component of food is a food additive that is subject to premarket approval by FDA, unless the substance is generally recognized as safe (GRAS) among experts. A substance that does not become a component of food, but that is used, for example, in preparing an ingredient of the food to give a different flavor, texture, or other characteristic in the food, may be a food additive.</td>
</tr>
<tr>
<td>Color Additive</td>
<td>A dye, pigment, or other substance that, when added or applied to a food, drug, or cosmetic or to the human body or any part thereof, is capable (alone or through reaction with another substance) of imparting a color thereto.</td>
</tr>
</tbody>
</table>
## Drug Databases

<table>
<thead>
<tr>
<th>Description</th>
<th>Database URL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drugs @ FDA</strong>: Search for approved drug labels</td>
<td><a href="http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm">www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm</a></td>
</tr>
<tr>
<td><strong>Daily Med Database</strong>: Search for labels when not available in Drugs@FDA</td>
<td><a href="https://dailymed.nlm.nih.gov/dailymed/index.cfm">https://dailymed.nlm.nih.gov/dailymed/index.cfm</a></td>
</tr>
<tr>
<td><strong>Approved Vaccines</strong></td>
<td><a href="http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/default.htm">www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/default.htm</a></td>
</tr>
<tr>
<td><strong>Generally Recognized As Safe (GRAS)</strong> which includes most Dietary Supplements, etc.</td>
<td><a href="http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/SCOGS/default.htm">www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/SCOGS/default.htm</a></td>
</tr>
<tr>
<td><strong>Food Additive List</strong></td>
<td><a href="http://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm091048.htm">www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm091048.htm</a></td>
</tr>
<tr>
<td><strong>Color Additive List</strong></td>
<td><a href="http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditiveInventories/ucm106626.htm">www.fda.gov/ForIndustry/ColorAdditives/ColorAdditiveInventories/ucm106626.htm</a></td>
</tr>
</tbody>
</table>
DEFINITIONS

Medical Devices
Instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article or component, part, or accessory, which is:

1) Recognized in the official National Formulary or the United States Pharmacopoeia;
2) Intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or other conditions

Intended to affect the structure or function of the body

AND

Does not achieve its primary intended purposes through chemical action within or on the body AND is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

Investigational Device Exemption (IDE)
An investigational device exemption (IDE) is an application that allows an investigational device to be used in order to collect safety and effectiveness data required to support a marketing application to the FDA. Significant risk devices require application to the FDA and receive an IDE number.

Abbreviated IDE
The protocol is NOT exempt from IDE regulations. Abbreviated IDE regulations must be followed. A risk determination is required to be made by the IRB and the use of the device must be found to be non-significant risk to follow abbreviated regulations. No submission is required to be submitted to the FDA, except as required in the abbreviated IDE regulations.

IDE Exempt
The protocol meets the criteria for exemption from IDE regulations. A risk determination is not required. No application to FDA is required.

Significant Risk
The use of an investigational device that presents a potential for serious risk to the health, safety or welfare of a subject due to its intended use AND is used:

• As an implant OR
• For supporting or sustaining human life OR
• Of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health OR
• Presents some other serious risk to patient’s health, safety, or welfare

Non-significant risk
The use of a device on a protocol that does not meet the definition of a significant risk.

Classes of Medical Devices
Knowing the class of the medical device (or a related medical device) can be helpful in establishing the level of risk designated by the FDA.
FDA Marketing Databases
1. 510K Exempt devices are listed on the FDA website: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/315.cfm
2. Devices at FDA: www.accessdata.fda.gov/scripts/cdrh/devicesatfda
**APPENDIX 3**  
IDENTIFYING SPONSORS, FUNDERS, AND COLLABORATORS IN INDS AND IDES

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Funder</th>
<th>Collaborator</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Takes responsibility for and initiates a clinical investigation. The sponsor may be an individual, pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator.</td>
<td>Entity/individual that is financially supportive of the research</td>
</tr>
<tr>
<td><strong>How to Identify</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| **IND or SR* IDE Acknowledgement** | Letter from FDA  
- Who is identified as the Sponsor | Protocol—Look for text that identifies:  
- Who funds the study  
- Who provides the investigational product  
- Disclosures of conflict of interest on the part of the investigator(s) | Protocol  
- Who is providing support to the study, as defined above  
- Who will receive information about or specimens from the subjects |
| **Protocol** | Look for text that identifies:  
- Who provides oversight of the study  
- To whom the PI team reports safety events, deviations, and exceptions | Consent—Look for text that identifies:  
- Who pays for subject injury  
- Who is listed as being responsible for early study termination  
- Who will receive information about the subjects  
- Who is providing oversight of the study | Consent  
- Who will receive information about the subjects |
| **Consent** | | |
| *SR = Significant risk device | | |
| **HSERA** | Sponsor Page, Regulatory Sponsor: Should be reflected here if funder or some other entity (e.g., industry, UPenn, or another institution) is the Sponsor  
OR  
Sponsor Page, IND Sponsor: Should be reflected here if the PI is a Sponsor-Investigator of an IND, IDE, or NSR | Sponsor Page, Funding Sponsor AND/OR  
Sponsor Page, Industry Sponsor | This might be reflected under the Sites page if this is a multicenter protocol.  
AND/OR  
This could also be reflected under Procedures Page, Data Disclosure |

**Note**—an entity/individual could also be any combination of the above: Sponsor/Funder/Collaborator, Sponsor/Funder, Sponsor/Collaborator, or Funder/Collaborator
OVERVIEW
The University Finance office encourages study teams to reimburse or compensate research subjects using the Greenphire ClinCard, a reloadable prepaid card. If a study team proposes to use Greenphire ClinCard the following is required:

HSERA Compensation section, Protocol, and the Informed consent payment section should all clearly state:

1. That ClinCard will be used as a payment option as well as the compensation schedule
2. Whether social security number will be collected for Clin Card purposes
   - If the study team has obtained a waiver for collecting social security number, this should be specified in HSERA and the protocol no the ICF.

Additional guidance at the University level is available from the Finance Office at the following link https://www.finance.upenn.edu/disbursements-accounts-payable/greenphies-clincard
OVERVIEW
The IAPS - International Affective Picture System- is a database of pictures designed to provide a standardized set of pictures for studying emotion and attention [1] that has been widely used in psychological research. When the IAPS will be used for Human Research at Penn, study teams often need guidance to appropriately incorporate the system into their protocol since the IAPS images can be extremely unpleasant.

Below is a sample of commonly requested revisions for a protocol and consent form utilizing this system:

1) Protocol - Methods - Study Instruments: Please identify the number of pleasant, neutral, and unpleasant images that will be presented to subjects. Please clearly justify why the use of unpleasant images is essential for the research.

2) Protocol - Study Procedures: IF IAPS WILL BE USED DURING LAB SESSIONS: Please comment on whether other staff, researchers, and/or subjects, may be exposed to the unpleasant images.

3) Protocol - Risk/Benefit Assessment: Please provide a plan for mitigating risks associated with viewing unpleasant images (e.g. thorough consent, debriefing process, and providing materials for counseling services).

4) Protocol - Informed Consent - Consent Process: Please confirm in this section that subjects will be reminded of risks associated with viewing unpleasant images and that they can end participation at any time. Please include the language below (stipulation #5) in the instructions provided prior to completing the IAPS. Additionally, please describe the debriefing process (stipulation #6).

5) Informed Consent Form: Please include the following language:

"If you decide to take part in this study, you will be asked to view a variety of pictures that have been categorized to be pleasant, neutral, or unpleasant. If any of the media presented should make you feel too uncomfortable to continue with the study, you are free to immediately withdraw your participation and leave without giving up credit or payment. The content of the pictures may include (insert description of image here. Suggested wording for unpleasant IAPs is as follows: images considered objectionable, such as sexually explicit and violent pictures that may be difficult to look at). To be clear: you may immediately end your participation if any aspect of the research procedure makes you too uncomfortable to continue. Lastly, if you have any discomfort or concerns after viewing the images, you are encouraged to call the principal investigator at (insert contact information for researcher(s)) or contact (list Psychological services with contact information, such as CAPS)."

6) General - Please develop an immediate debrief for the end of the study that includes information for CAPS and other counseling services available to the Penn community. Please upload a debriefing form for IRB review.