Penn IRB SOP Version 16
Summary of Substantive Changes

Applicable Sections	Summary of Changes	Rationale for Changes
Throughout	Revised mentions of HSERA to eIRB	eIRB replaces HSERA on 2/9/26
Throughout	Revised mentions of modification submissions to amendment	To align with eIRB terminology
GA 101 AUTHORITY, PURPOSE AND SCOPE	Revised the number of IRB committees from 9 to 10.	Penn IRB obtained a new committee.
GA 102 ACTIVITIES REQUIRING IRB REVIEW	**Added new language:** 3.2 Activities Not Subject to IRB Review Added language to reflect that if a determination of not human subjects research is desired from the IRB, it should be submitted in the eIRB system.	The eIRB system now contains electronic forms for not human research determinations and quality improvement applications. The IRB is not accepting these requests via email any longer.
GA 107 SIGNATORY AUTHORITY	**Added new language:** 3.2 Results of Reviews, Actions and Decisions Electronic signatures via the Penn eIRB system (eIRB) are considered valid. eIRB is password protected and limited to only those individuals directly connected with a protocol and the appropriate regulatory staff. Penn faculty, staff, and IRB members use their secure log-in to access eIRB. Individuals with the appropriately designated permissions use the eIRB Decision Form to electronically provide approval (or alternate determination) of protocol submissions. eIRB records the individual by name and their electronic approval (i.e., electronic signature), and all actions taken by that individual.	IRB letters will no longer be signed using Adobe. When users process a submission (approval or otherwise) in eIRB, this is documented with their name and date in the system. IRB letters will list the name of the IRB staff person who screened and processed the submission and drafted the letter.

	3.3 Routine Internal Correspondence Any action, letter, memo or e-mail between the IRB or administrative staff and the faculty or staff of the University that provides information concerning the review of research protocols by the IRB or staff and which do not imply or appear to imply approval of this activity may be signed by the IRB staff member. Signature is designated by the IRB staff member's name on the letter. **3.4 Correspondence with External Agencies** Official letters or memos sent to agencies of the federal government, funding agencies (whether private or public) or their agents will be signed by the Vice Provost for Research or designee. Letters or memos may be signed with an electronic signature.	
FO 304 DOCUMENTS AND DOCUMENT MANAGEMENT	**Added new language:** 3.1 Document Retention. The IRB must retain all records regarding a project or protocol subject to HIPAA regulations for at least six (6) years, including any issued waivers of HIPAA authorization.	Updated to align with the HIPAA regulatory requirements.
FO 304 DOCUMENTS AND DOCUMENT MANAGEMENT	**Added new language:** 3.3 Application Field Revisions Edit access to an eIRB protocol application is limited to only those individuals directly connected with a protocol and designated to have edit access as well as the IRB staff. Individuals with the designated role of IRB Admin in the eIRB system have permissions to make revisions to application responses but may only do so in limited circumstances. Circumstances under which this is appropriate includes when the field is critical for IRB documentation and determinations. When making revisions to such fields, the IRB staff are required to add a comment directly on the item to document their change and the reason for the change.	Updated to add a policy on when the IRB will edit an eIRB protocol application.

	If the IRB staff receive a request from the study team for the IRB staff to make a change to their eIRB protocol application (such as to add a staff member or give a staff member edit access), it must be in writing. Likewise, the IRB staff should PDF a copy of the request, and upload it into the field comment. IRB staff are not responsible for making changes to the application that are stipulated by the IRB. This remains the responsibility of the study team.	
RR 401 B EXEMPT AND RESEARCH UNDERGOING LIMITED REVIEW PROCEDURES	**Revised and added language:** 3.3 Execution of Exempt Research 3.3.1 Continuing Review. Annual continuing review is **not** required for research granted exemption. Investigators ~~may~~ should close the research protocol when research is completed. 3.3.2. Annual Check-Ins. An administrative annual check-in will be prompted yearly for research granted exemption or limited review. The annual check-in form will prompt confirmation that the protocol is still active. Failure to complete this for three (3) consecutive years will prompt study closure.	Updated to reflect that investigators should close their protocols that have undergone exempt level review. Updated to add requirements for annual check-ins. Updated to note that failure to complete annual check-ins for three years in a row will lead to automatic study closure.
RR 402 EXPEDITED REVIEW	**Revised language:** 3.4.3 Approval of Participating Sites The Director, Associate Directors, or other designated IRB members may use the expedited review procedures to review external site requests to rely on the Penn IRB's approval. These requests to add external sites to the parent record may be submitted as ~~as modifications~~an amendment to previously approved research. Review of these requests is necessary if the external organization has agreed to rely on the Penn IRB through an IRB authorization agreement or under the conditions of an approved cooperative agreement. The Penn IRB, as the IRB of Record, will review the participating site's initial application in eIRB, which shall include information regarding the participating site's research team, the nature of their participation in the	Updated to reflect that a participating site's initial application is no longer submitted via a supplemental form in an HSERA modification submission to the IRB. This application is now an initial application electronic form for the relying site to complete.

	multi-site protocol, and the results of any local context review conducted by the external organization's IRB or Human Research Protections Program. This may include revisions to the IRB approved consent form.	
RR 403 INITIAL REVIEWS: CRITERIA FOR IRB APPROVAL	**Added new language:** 3.4 Reliance on Other IRBs for Review and Approval of Research Conducted at the University of Pennsylvania Post-approval amendments impacting applicable local context requirements are subject to Penn IRB review. 3.4.2. Annual Check-Ins. An administrative annual check-in will be prompted yearly in the IRB system for research relying on external IRBs. The annual check-in form will prompt confirmation that the protocol is still active. For research determined to require continuing review by the IRB of Record, the form will prompt submission of updated approval dates. Failure to complete this for three (3) consecutive years will prompt closure of the record.	Added text to reflect current requirements that if there are changes impacting *local context* for studies relying on external IRBs, they should be submitted for IRB review. This requirement has not changed, but text has been added to make this clearer. The Penn IRB continued to not require submission of protocol amendments not impacting local context. Updated to add requirements for annual check-ins for studies relying on external IRBs. Updated to note that failure to complete annual check-ins for three years in a row will lead to automatic study closure.

RR 404 ONGOING REVIEW	**Added new language:** 3.1 Ongoing Review for Minimal Risk Research An administrative annual check-in will be prompted yearly for research reviewed at the expedited level, but not requiring continuing review. The annual check-in form will prompt confirmation that the protocol is still active. Failure to complete this for three (3) consecutive years will prompt study closure.	Updated to add requirements for annual check-ins for studies undergoing expedited review, when continuing review is not required. Updated to note that failure to complete annual check-ins for three years in a row will lead to automatic study closure.
RR 404 ONGOING REVIEW	**Added new language:** 3.4 Modifications Exceptions (Prospective Deviations) Exception requests shall be submitted through ~~HS-ERA~~eIRB for electronic protocols. Time sensitive exception requests ~~requiring approval within 24 hours should be submitted via email and must include the IRB exception request form.~~are flagged as urgent in eIRB, negating the need to send them to the IRB via email.	Updated to reflect that time sensitive exception requests should be submitted in eIRB.

RR 405 CRITERIA FOR RENEWAL	**Deleted language:** 3.3 Criteria for Renewal 3.3.2 Currently Approved Protocol including any amendments to Protocol since initial review. A copy of the protocol will be available to the primary reviewer of the continuing review. Amendments to a research protocol should be submitted on an ongoing basis during the course of the study. They may be submitted at the time of continuing review~~, but only for submissions that are paper based~~. A separate cover letter describing the amendment and all appropriate documentation (revised consent form) must accompany the continuing review application. Electronic submissions ~~do not~~ allow for amendments with a continuing review submission. ~~The electronic submission system requires two independent submissions for continuing review and modifications. Concurrent continuing review and modification submissions are not recommended within the electronic submission due to technical issues that arise.~~	Removed language around submitting concurrent amendments and continuing reviews. eIRB allows a combined amendment and continuing review submission process.

RR 406 STUDY COMPLETION	**Added new language:** 3.1 Determining When a Project can be Closed 3.1.3. Minimal risk research not requiring continuing review and studies relying on external IRBs: These protocols will be closed administratively by the IRB if the study team is non-compliant with submitting an annual check-in for three (3) consecutive years. The study team will be notified of study closure in these cases and must cease research activity on the project. 3.2 Completion Reports Final Reports should be submitted promptly within 30 days after completion of the study via a closure submission in the system. Final reports may be submitted in any format that provides adequate information about the status of the study, such as emails, letters, etc. Final reports may be submitted by the investigator or his/her/their designee. The IRB Staff will review all reports of study completion and, if needed, request further information from the investigator to clarify any questions that may arise. Notice of the submission of Final Reports or closures will be reported to the Board via the minutes and copies of the reports and any supplement information will be available for the members. Closure submissions in the IRB system for protocols qualifying for exempt level review are administrative in nature and do not route to the IRB for review. 3.3 Re-opening a Completed Protocol A study team may request to re-open a completed or administratively closed protocol via the appropriate mechanism in the IRB system. The IRB will review the request and communicate any requirements with the study team, as needed. If it is determined appropriate to re-open the study, the IRB will update the overall status of the protocol. If it is not appropriate to re-open the study, the IRB will instruct the study team to draft a new protocol.	Updated to note that failure to complete annual check-ins for three years in a row will lead to automatic study closure. Updated to reflect that all closures are submitted via the eIRB system. Closures for exempt protocols do not undergo IRB review. Updated to reflect new processes for requesting a completed study be re-opened. This may be done within the eIRB system.

RR 407 CATEGORIES OF ACTION	**Revised language:** 3.1 Determinations: Initial Review • Administratively Finalized: When additional documentation is needed before research activity may begin (i.e. approval from other sites, etc.). Also applies for studies with industry funding, where a contract is not yet executed, and enrollment should not commence • ~~Approved Pending Contract: Applies for studies with industry funding, where a contract is not yet executed, and enrollment should not commence~~	Updated to reflect that the IRB is no longer using the status of Approved Contract Pending.