

How to Submit: Initial IRB Application

Step by Step Guide for Researchers and Support Staff

Please note: There are references to “the IRB website” throughout this guidance. The site we are referring to is always www.upenn.edu/IRB.

When we talk about “HSERA” we are referring to the electronic submission system for human research at Penn. It is important to know that these are 2 separate internet locations. Use of both sites is required for successfully submitting to the IRB.

*This PDF is bookmarked for quick navigation

Covered here:

- Using the IRB Website (www.upenn.edu/IRB)
- Using IRB Protocol and Consent Templates
- Using HSERA

Version 2024

USING THE IRB WEBSITE TO GUIDE YOUR SUBMISSION CREATION PROCESS

- Researchers and Research staff should reference the IRB website for instruction before logging on to HSERA to create submissions

- Go to www.upenn.edu/IRB

- Use the guidance and templates provided by the IRB to build the documents for your project before you submit in HSERA

- A link to HSERA is provided on the home page for convenience

- If you work on multiple human research projects we suggest bookmarking and visiting the IRB website often to stay up to date on the latest news

The screenshot shows the Penn Biomedical Research website. At the top left is the Penn logo with the text 'Human Research Protections Program'. To the right of the logo are navigation links: 'SOCIAL BEHAVIORAL RESEARCH', 'ACCESS HSERA', 'IRB MEMBERS', and 'STAFF DIRECTORY'. Below these is a dark blue navigation bar with the text 'Biomedical Research' and a search bar. The search bar contains the text 'Use the search bar to find what you're looking for'. The navigation bar includes links for 'HOME', 'HOW TO SUBMIT', 'FORMS & TEMPLATES', 'BIOMEDICAL GUIDANCE', 'STUDENT RESEARCHERS', 'FAQS', and 'SEARCH'. Below the navigation bar, the page is organized into three columns. The left column is titled 'Initial Submission' and includes links for 'Is IRB Review Required?', 'QI/PI Project Guidance', 'IRB Review for Federal or State Grants', 'Levels of IRB Review', 'Biomedical Submission Completion Guidance', 'Data and Safety Monitoring', 'Other Penn Reviewing Entities', and '2018 Common Rule'. The middle column is titled 'Single IRB' and includes links for 'Request for Penn to Serve as sIRB', 'IRB Reliance Agreements', and 'Requests to Rely'. Below this is a 'Modifications' section and a 'Continuing Review' section with a link for 'Respond to Conditional Re-approval'. The right column is titled 'Deviations' and includes links for 'Respond to a Compliance Audit Report', 'Exception Requests', 'Reportable Events', 'Reportable Event Guidance', 'Closure', 'Treatment Use of Investigational Agent', and 'Humanitarian Use Devices'. A yellow box with an arrow points to the 'ACCESS HSERA' link, containing the text 'Click This Link to Log On & Access HS-ERA'. A red box with an arrow points to the 'FORMS & TEMPLATES' link, containing the text 'Click here to download IRB Forms and Consent & Protocol Templates'. A red box around the search bar contains the text 'Use the search bar to find what you're looking for'.

Click This Link to Log On & Access HS-ERA

SOCIAL BEHAVIORAL RESEARCH

ACCESS HSERA

IRB MEMBERS

STAFF DIRECTORY

Biomedical Research

HOME

HOW TO SUBMIT

FORMS & TEMPLATES

BIOMEDICAL GUIDANCE

STUDENT RESEARCHERS

FAQS

SEARCH

Use the search bar to find what you're looking for

Click here to download IRB Forms and Consent & Protocol Templates

USING THE IRB WEBSITE TO GUIDE YOUR SUBMISSION CREATION PROCESS

- On the Forms & Templates page, filter for protocol documents

- Use the appropriate template for your type of project

- If you aren't sure if your project requires IRB review, download and complete the **Human Subjects Research Determination Form** and send to PROVOST-IRB@pobox.upenn.edu for a consultation.

Form Quick Finder

This page is a Penn researcher resource of IRB forms and document templates commonly utilized in IRB submissions.

Filters

RESEARCH TYPE

- Biomedical Research
- Social Behavioral Research

DOCUMENT TYPE

- Consent Templates
- Continuing Review
- Modifications
- Protocol Templates
- Recently Updated
- Reliance/sIRB Forms
- Supplemental Forms
- Uncategorized

Search terms...

Protocol Template Social Behavioral

SOCIAL BEHAVIORAL RESEARCH

PROTOCOL TEMPLATES

FEBRUARY 8, 2023

Protocol Template Retrospective Study

BIOMEDICAL RESEARCH

SOCIAL BEHAVIORAL RESEARCH

PROTOCOL TEMPLATES

FEBRUARY 8, 2023

Protocol Template Clinical Trial

BIOMEDICAL RESEARCH

PROTOCOL TEMPLATES

FEBRUARY 8, 2023

USING THE IRB WEBSITE TO GUIDE YOUR SUBMISSION CREATION PROCESS

- On the Forms & Templates page, filter for Consent Templates
- Download the templates that best apply to your study
- The templates have the basic required elements of consent which should be revised to describe your study.
- Additional language may be required depending on your study design (e.g. use of PHI will require HIPAA language, genetic testing will require GINA language etc.)

- Recently Updated
- Reliance/sIRB Forms
- Supplemental Forms
- Uncategorized

Single Patient Expanded Access Consent Template

BIOMEDICAL RESEARCH CONSENT TEMPLATES

FEBRUARY 8, 2023

Penn Medicine HIPAA Language Template

BIOMEDICAL RESEARCH SOCIAL BEHAVIORAL RESEARCH CONSENT TEMPLATES

FEBRUARY 8, 2023

Penn Dental HIPAA Language Template

BIOMEDICAL RESEARCH SOCIAL BEHAVIORAL RESEARCH CONSENT TEMPLATES

FEBRUARY 8, 2023

Parental Permission Signature Block Template

BIOMEDICAL RESEARCH SOCIAL BEHAVIORAL RESEARCH CONSENT TEMPLATES

FEBRUARY 8, 2023

Informed Consent Form Template (Social Behavioral Research)

SOCIAL BEHAVIORAL RESEARCH CONSENT TEMPLATES

FEBRUARY 8, 2023

Informed Consent Form Template (Biomedical)

BIOMEDICAL RESEARCH CONSENT TEMPLATES

FEBRUARY 8, 2023

USING HSERA (HUMAN SUBJECTS ELECTRONIC RESEARCH APPLICATION)

- Once your basic study documents are ready, log in to HSERA to create your application

- The front page of HSERA has a menu of links along the left side for creating and managing your submissions

-The content in the center of the page shows :

“My Submissions” = your IRB submissions pending review

“My Requests” = your CHPS requests pending review

“My Work In Progress” = drafts you are working on for both IRB and CHPS

The screenshot shows the HSERA web application interface. The browser address bar indicates the URL: <https://hsera.apps.upenn.edu/hsProtocol/jsp/fast2.do>. The page features a dark blue sidebar with the Penn University of Pennsylvania logo and the text "IRB Submission". The main content area is titled "My IRB Submissions and CTRC Request Home Page" and includes sections for "My Submissions", "My Requests", and "My Work In Progress". A "HSERA News" section is also present, dated August 1, 2016, with a detailed announcement about new requirements for electronic data protection for research involving directly-identifiable protected health information (PHI).

My Submissions
No Submissions within the last 90 days.

My Requests
No requests within the last 90 days.

My Work In Progress
6 Submissions to be completed (3 Modification, 1 Continuing Review, 2 Initial Review, 0 Reportable Event)
1 CTRC requests to be completed

HSERA News
August 1, 2016
The Penn IRB has released a new document outlining requirements for electronic data protection for research involving the use of directly-identifiable protected health information. A companion guide has also been developed that outlines key features of IRB-approved mechanisms for data storage and transmission that comply with the new requirements. [Click here](#) to download copies from the IRB website. The IRB will be deferring to these requirements as of August 1, 2016. All new submissions received after August 1, 2016 that involve the use of directly-identifiable electronic protected health information will be required to include data confidentiality plans that align with the requirements outlined in this new document. A description of your data confidentiality plan and how it aligns with these new requirements should be included in response to the Subject Confidentiality question in HS-ERA. Please Note: Changes to the wording of this question in HSERA are in production to better align with the new guidelines, however the timeline for release has yet to be determined. Please note that after the August 1, 2016 release date, the IRB support staff will be reminding all research teams working on studies that involve the use of directly identifiable PHI to assess their current data protection plan to determine if modifications are needed. While a reminder note may be included in your continuing review approval letter, the IRB will not withhold or delay re-approval based on the current description of data protection plans.

USING HSERA (HUMAN SUBJECTS ELECTRONIC RESEARCH APPLICATION)

- To create a new study Click "Create" under "My submissions"

-Review the information on this screen shot to get an idea of how to navigate with the HSERA menu

- Please note that the IRB staff and members are provided with navigation links in the HSERA menu that may not appear for typical users. In this training we are focusing on the universal navigation links that all users have access to although the additional links may still appear in the screenshots.

IRB Submission

- ▼ **My submissions**
 - Create
 - Manage drafts
 - Items to be resubmitted
- ▼ **Submissions history**
 - Recent
 - All
- ▼ **My submission approvals**
 - View pending
 - View history
- ▶ **My CTRC requests**
- ▶ **My CTRC approvals**
- ▶ **System administrator**
- ▶ **ORA administrators**
- ▶ **Board Members**
- ▼ **Resources**
 - IRB Homepage
 - IRB Deadlines
 - IRB Forms
 - ORA Important Links
 - Penn Online Directory
 - CTRC Homepage

Click "Create" to make something new

Click "Manage Drafts" to keep working on something you already created but did not submit. A new submission will automatically appear in manage drafts after you complete the first page.

Click "Items to be resubmitted" to work on a submission that the IRB sent back to your team after performing a review.

Both links under "Submission History" will allow you to go back and view any submission for studies you are listed as personnel. Recent shows submissions from the last 90 days. This is a view only access.

"Submission Approvals" section is for Principal Investigators and Departmental Approvers only.

Use the resources links to :
-go back to the IRB website
-view the convened board meeting schedule
-go to the forms page on the IRB website etc..

USING HSERA (HUMAN SUBJECTS ELECTRONIC RESEARCH APPLICATION)

- After clicking "Create" you will be brought to a new menu screen. Choose "Initial Review" to begin an application for submitting a brand new study

- The other application types are also available on this page.

- After a new study receives approval, any subsequent changes must be submitted by creating Modification submissions. This includes Personnel changes.

- If your protocol requires continuing review, you can renew your protocol annually by creating a Continuing Review application here.

Penn
UNIVERSITY of PENNSYLVANIA

IRB Submission

- ▼ My submissions
 - **Create**
 - Manage drafts
 - Items to be resubmitted
- ▼ Submissions history
 - Recent
 - All
- ▶ My submission approvals
- ▶ My CTRC requests
- ▶ My CTRC approvals
- ▶ System administrator
- ▶ ORA administrators
- ▶ Board Members
- ▼ Resources
 - IRB Homepage
 - IRB Deadlines
 - IRB Forms
 - ORA Important Links
 - Penn Online Directory
 - CTRC Homepage

Protocol Submission Type - Choose

Activities that Do Not Meet the Regulatory Definition of Human Research
The first question one should consider when assessing the requirement for IRB review is whether the activity meets the regulatory definition of human research. Anyone unsure about IRB review requirements and whether their proposed activity constitutes "human research" requiring IRB review should contact the Office of Regulatory Affairs. The IRB staff will determine if the activity is human research. If an activity does not meet the regulatory definition of human research, the IRB will, upon request, issue a letter stating that the project does not require IRB review or approval. Refer to the IRB Guidance: Is IRB Review Required?

Initial Review
Research must be reviewed by a convened meeting of the IRB unless the research is **exempt or is eligible for expedited review**. Final review category and submission requirements will be determined by the IRB.

Continuing Review
Continuing Review for convened board or expedited review
The IRB Application for Continuing Review must be submitted no later than six weeks prior to the expiration date for full board review and no later than two weeks for expedited review.

Modification
Modification of approved or existing protocol
Changes in approved research, during the period for which approval has already been given, may not be initiated without prior IRB review (or expedited review, where appropriate) and approval except where necessary to eliminate apparent immediate hazards to human subjects.

Deviation
Deviations from the approved or existing protocol
An unintentional action or process that departs from the IRB approved study protocol and identified retrospectively, after the event occurred. If the impact on the protocol disrupts the study design or compromises the safety and welfare of the subjects, the deviation must be reported to the IRB within 10 business days.

Exception
Exception Requests from the approved or existing protocol
A one time, intentional action or process that departs from the IRB approved study protocol, intended for one occurrence. If the action disrupts the study progress, such that the study design and results would be compromised, and the action compromises the safety and welfare of study subjects, prior documented IRB approval is required.

Reportable Event
Reportable Event posing risks to subjects or others including adverse events
The IRB requires reporting of events that are: (1) unforeseen and (2) indicate that participants or others are at increased risk of harm. If yes to both, the problem is considered a Reportable Event involving risks to participants or others.

USING HSERA (HUMAN SUBJECTS ELECTRONIC RESEARCH APPLICATION)

- After clicking “Initial Review” you will be brought to a new menu screen.
- You are given the option of opening a blank application or opening an application based on one of your existing studies
- You may only have one draft per protocol and will not be able to create a second draft for the same study.
- This guidance document is based on choosing “New Submission”

New Initial Review: Choose

[New submission](#)

This option will allow you to begin a new protocol for initial review starting from a blank submission form.

[Based on an existing protocol](#)

This option will allow you to begin a new protocol for initial review based on an existing protocol on which you are listed. You should choose this option only for new research, **NOT** for modifying or amending an existing protocol.

[Cancel](#)

USING HSERA (HUMAN SUBJECTS ELECTRONIC RESEARCH APPLICATION)

- After clicking "new submission" you are brought to the first screener page for the application

- Answering the screener questions will determine the level of specificity of your application.

- Step one is to establish if your project qualifies as "Exempt"

- Research that is exempt is minimal risk and falls into one of 8 specific categories. **Some exempt research requires modifications after initial review, if the IRB conducts a Limited Review. Your letter will inform you if modifications are required.**

- **An Exempt application is the shortest application.** If you submit an exempt application for non-exempt research you may be required to re-submit the full application

The screenshot shows the Penn University of Pennsylvania IRB Submission application interface. At the top left is the Penn logo. Below it, the text "IRB Submission" is displayed in large yellow font. Underneath, it says "Welcome WIRTANEN, EMILY A". A navigation menu on the left side includes sections for "My submissions" (with sub-items: Create, Manage drafts, Items to be resubmitted), "Submissions history" (with sub-items: Recent, All), "My submission approvals", "My CTRC requests", "My CTRC approvals", "System administrator", "ORA administrators", "Board Members", and "Resources" (with sub-items: Technical support, IRB Homepage, IRB Deadlines, IRB Forms, ORA Important Links, Penn Online Directory, CTRC Homepage).

The screenshot shows the "Human Subjects Questionnaire" application interface. At the top, there are "Help" and "Log out" links. The main heading is "Human Subjects Questionnaire". Below this, a question is posed: "Question: Does your submission qualify for exemption from IRB review?". The text below the question reads: "Read the text for each category carefully. To qualify for an exemption in a specific category *all green bulleted items in that category must be true.*". There are two instructions: "For research involving FDA regulated products, choose Category 6." and "For research involving the use of cadavers, choose Category 4.". A link for "Claim of Exemption Instructions" is provided. A note states: "Note: The text for this question is quite long. You must scroll down to the bottom of the page to click the continue button." Below the question, there are two radio button options: "No - This research project does not qualify for exemption from IRB review." and "Category 1". A yellow information icon is located at the bottom of the question text area. A green callout box points to this icon with the text: "These yellow icons appear throughout the HSERA application. Click them to view helpful text." A blue callout box points to the "Category 1" option with the text: "Scroll down to review descriptions of all 6 Exemption categories. You may choose ONE category that best applies to your study. If your study is not exempt, click the radial button for 'No' and scroll to the bottom to click 'continue'".

USING HSERA (HUMAN SUBJECTS ELECTRONIC RESEARCH APPLICATION)

- If your study is not “Exempt”, the next step is to determine if it is “Expedited”

- It is possible to submit an exempt application but the IRB may determine that your research qualifies as expedited.

- “Expedited” research is minimal risk and fits into one or more of 7 categories

- “Expedited” research requires modifications, deviations, and reportable events to be submitted to the IRB. Continuing review is not required unless you are informed by the IRB (e.g., for FDA regulated research)

- “Expedited” and “Exempt” research is not sent to the monthly convened board meetings for review. Instead, it is screened by qualified IRB staff members and approved by one of the IRB directors or Chairs.

The screenshot shows the Penn University of Pennsylvania IRB Submission portal. The navigation menu includes:

- My submissions
 - Create
 - Manage drafts
 - Items to be resubmitted
- Submissions history
 - Recent
 - All
- My submission approvals
- My CTRC requests
- My CTRC approvals
 - View pending
 - View history
- System administrator
- ORA administrators
- Board Members
- Resources
 - Technical support
 - IRB Homepage
 - IRB Deadlines
 - IRB Forms
 - ORA Important Links
 - Penn Online Directory
 - CTRC Homepage

The screenshot shows the Human Subjects Questionnaire page. The question is: "Does your submission qualify for expedited review?". The text explains that an expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110. The applicability section states that research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories listed below, qualify for expedited review. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review. Categories one (1) through seven (7) pertain to both initial and continuing IRB review. Further information on expedited review can be found on the Office of Regulatory Affairs web site, see [Expedited Review of Protocols Involving Human Subjects](#). The page includes a list of categories with checkboxes:

- No - This research study does not qualify for expedited review
- Category 1 - Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture (a) or (b) is met.
 - a. Research on collection of blood samples by finger stick, heel stick, ear stick, or venipuncture is required. (Not applicable to research involving collection of blood samples by finger stick, heel stick, ear stick, or venipuncture for the purpose of the study, if the research is exempt from the requirements of Part 812) is not a medical device.
 - b. Research on collection of blood samples by finger stick, heel stick, ear stick, or venipuncture is not a medical device.
- Category 2 - Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

Scroll down to review descriptions of all 7 Expedited categories. You should choose all categories that apply to your study. If your study is not expedited, click the radial button for “No” and scroll to the bottom to click “continue”




USING HSERA (HUMAN SUBJECTS ELECTRONIC RESEARCH APPLICATION)

--BASIC INFO--

- After completing the screening pages you will be brought to the first page of the application

- Once you start this page your draft will show in your "manage drafts" until you complete the submission by clicking "I Accept" on the "Confirmation" page

- On the "Basic Info" page you will name and describe your study



The banner at the top will highlight your progress. When the "Confirmation" page is highlighted you are on the final page

- ▶ My submission approvals
- ▶ My CTRC requests
- ▶ My CTRC approvals
- ▶ System administrator
- ▶ ORA administrators
- ▶ Board Members
- ▼ Resources
 - Technical support
 - IRB Homepage
 - IRB Deadlines
 - IRB Forms
 - ORA Important Links
 - Penn Online Directory
 - CTRC Homepage

- Basic Info
- Personnel
- More
- Sponsors
- Sites
- Protocol
- Populations
- Procedures
- Consent
- Risk/Benefit
- Confirmation

Protocol Form - Basic Info

Next Save Draft

Click "Next" to move to the next page after you have completed this page. Clicking "Save Draft" will save your progress and take you out of the application

You are about to create a new Human s

1. Enter basic protocol information
2. Choose the submission type
3. Supply the information and supporting documents necessary for the submission
4. Complete the submission

Important points to keep in mind:

- An asterisk (*) means a field is required. You must complete all fields on a given page before you can advance to the next page.
- When you have finished entering information on a page, click **Next**. This saves your work and proceeds to the next section, allowing you to continue entering information about your protocol submission
- If you are unable to complete a page, click **Save Draft**. This will save your submission and return you to the Homepage allowing you to finish at another time.
 - Page must be error free before you can use 'Save Draft'
- Some information on this application is retrieved from external systems and any changes will need to be made within the source system. These include:
 - Demographic data (ie. address, phone, email, etc) - required changes must be made in the university's online directory, Penn Community.
 - Training data - Training data is from Knowledge link. the university's online training system. To correct training information, contact the IRB.
 - Sponsor Information - Sponsor i es or additions to pennerahelp@lists.upenn.edu.

Protocol Information

Protocol title*

Short Title*

Brief description of the protocol*

Please provide, in 500 characters or less, a description of the purpose of the study, the targeted population and the procedures/interactions/interventions necessary for participation.

Submission type*

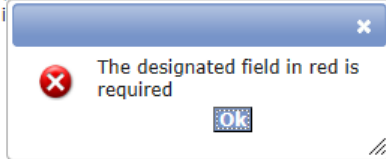
- Biomedical Research
- Social and Behavioral Sciences

The answer to this question will determine the content of the page that is currently displayed as "More" in the top banner

Resubmission*

Is this a response to an already submitted Initial Review?

No



The system will prevent you from moving to the next page if there are errors or blanks

USING HSERA (HUMAN SUBJECTS ELECTRONIC RESEARCH APPLICATION)

--PERSONNEL--

- After completing the Basic Info Page you will complete the personnel page

- The Principal Investigator (PI) must be an active Penn Faculty member who is available to review and sign off on every submission for the study

- Study contacts are study team members who can create and edit submissions to the IRB

- The "other investigator" slot is where students should name themselves on their projects since they cannot serve as PI

- It is important to keep the Personnel page up to date throughout the study

Basic Info Personnel Bio Sponsors Center

Protocol Form - Study Personnel

Previous Next Save Draft
Page must be error free before you can use 'Save Draft'

Principal Investigator* Change Remove

Name	YOOS, JESSICA L
Penn ID	17750340
Department/School/Division	10250 - Institutional Review Board
Campus address, mail code	
Address	Human Research Protections Program 3600 Civic Center Blvd 9th Floor
City	Philadelphia
State	PA
Zip	19104-0000
Phone	
Fax	
Pager	
Email	
Human Research Training	Complete
Name of course completed	CITI Protection of Human Subjects Research Tr
Good Clinical Practices Training ⓘ	Incomplete
Training Expiration Date	Expired

Study Contacts Add

Complete if different from PI - Up to Three Allowed.
The contacts listed here will have viewing and editing capabilities to th

Other Investigator Set

Name	
Penn ID	
Department/School/Division	-
Campus address, mail code	
Address	

Click the green button to bring up the list of Penn affiliates to choose from. You can choose 1 PI. The PI can create and edit submissions.

All study team members must have complete and current CITI Human participants Research training. If this area shows "Incomplete" for any person on your study team, the IRB will not approve your study without supporting documentation of training.

Clinical Trials also require Good Clinical Practice training.

You can choose up to 3 study contacts for a study. Study contacts can create and edit submissions.

You can choose 1 Other Investigator as a CO-PI. The CO-PI can create and edit submissions.

USING HSERA (HUMAN SUBJECTS ELECTRONIC RESEARCH APPLICATION)

Personnel Page Continued:

- The Departmental Approver assigned to your Responsible ORG must approve your initial application before the IRB receives it. Be sure to contact that person to avoid delays.

- Avoid using the Department Code 2100, as there is no assigned Department Chair

Responsible Org (Department/School/Division)

[Change](#) [Remove](#)

Pick the University unit that is supporting this research if different from the PI's department

If your Org is not available for selection, please contact hsera_help@lists.upenn.edu and identify the approver (Dept Chair) for your Org so that it can be updated for you.

10643 - Lancaster General Health Consolidated

Key Study Personnel

[Add](#)

Key personnel are defined as individuals who contribute to the study in a substantive, measurable way. Do not list personnel already listed above.

Penn Intellectual Property*

To the best of the Principal Investigator's knowledge, does this protocol involve the testing, development, or use of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania? Please refer to the [Patent and Tangible Research Property Policies and Procedures](#).

Yes

No

Certification

I have conferred with the Principal Investigator and to the best of his/her knowledge, confirm that the information provided in the above questions are correct.

[Previous](#)

[Next](#)

[Save Draft](#)

Page must be error free before you can use 'Save Draft'

The ORG chosen here will determine who the Departmental Approver will be. Please consult your business administrator before choosing.

Key Personnel are other members of the study team who are engaged in human research. There is no limit to the number of Key Personnel that may be added. Key personnel CANNOT create or edit submissions

Intellectual Property associated with this protocol should be disclosed here.

Additionally, all research staff who are responsible for the design, conduct, & reporting of the protocol must disclose any significant financial interests in the RIA system.

Please contact the Research Integrity Office for more information.

Click "Next" to move to the next page after you have completed this page.
Clicking "Save Draft" will save your progress and take you out of the application

--BIO/SOC PAGE--

After completing the Personnel page, the next page depends on the answer provided in the first page of the application

Biomedical
Research



Bio Page:

Social &
Behavioral
Research



Soc. Page:

--BIO/SOC PAGE Cont.--

The Bio/Soc page will identify any additional institutional ancillary reviews that are needed for your study.

The Radial buttons chosen on this page will send email notifications to other Penn offices.

BIO Page

- **Questions on the BIO page include but are not limited to:**
- Drugs/Devices
- IND/IDE review
- Radiation Exposure (RRSC Review)
- Gene Transfer (IBC Review)
- Human Source Material
- CACTIS and CT procedures
- CAMRIS and MRI procedures
- Cancer Related Research (CTSRMC Review)
- Medical Information disclosure
- Path/lab Medicine services
- Apheresis/Transfusion
- UPHS Services

SOC Page

- **Questions on the SOC page include but are not limited to:**
- Description of survey instruments
- Description of study groups
- Methods for assigning participants

--SPONSORS CONT.--

In addition to Penn Budgeting information, the sponsor page requires specific information about funding for your study.

Funding Sponsors [Add](#)

Identify the agency, organization, company or person providing funds for the research study. The IRB charges fees to cover the costs associated with the review of industry sponsored investigational drug and device trials.

Name	UNIVERSITY OF PENNSYLVANIA
Type	UPENN Internal

[Remove](#)

Click the green "Add" button to choose from a list of sponsors. If your sponsor is not listed, please contact the HSERA help desk.

Funding sponsors billing address

If you have selected a commercial or industry sponsor, please provide the appropriate address and contact information for the Sponsor for the purposes of billing for IRB review fees (initial review, continuing review and convened modification fees apply here). If the Sponsor is not industry/commercial, this information is not necessary to provide with your application.

Funding sponsors gift

Is this research being funded by a philanthropic gift?

- Yes
 No

If the answer to this question is "yes", University Policy requires that the gift agreement signed by the donor includes a disclosure that iterates an individual gift may not fund a specific research protocol on which they or their family member wishes to participate. Please contact the Director of the IRB, Tracy Ziolek (ziolekt@upenn.edu or 215-746-6272) if you have any questions.

Please note: If the initial answer to this question is "no", but a gift is received during the conduct of this research study, the answer must be updated to "yes" upon receipt of the gift.

--SPONSORS CONT.--

For Biomedical studies using investigational drugs and devices, the Sponsor page captures the regulatory IND/IDE sponsor information (the entity or person responsible for study oversight).

Regulatory Sponsor allows the submitter to identify an entity as the sponsor (e.g., Merck, or University of Pennsylvania).

IND Sponsor allows the submitter to identify a Faculty member as the Regulatory Sponsor.

Sponsors should also disclose any financial interests in the RIA System.

Regulatory Sponsor Set

Also called the regulatory sponsor, this is the agency, organization, company or person primarily responsible for initiating and overseeing the research and ensuring the study complies with research standards and federal regulations. For clinical trials (studies involving drugs or devices) this is typically the FDA IND holder, for device studies, this is the FDA IDE holder.

- For industry-sponsored trials, typically the pharmaceutical/device/biotechnology company is the regulatory sponsor.
- For non-industry sponsored trials, the regulatory sponsor is typically the NIH or an NIH-designated entity (e.g. for the NCI, CTEP can be the regulatory sponsor if that entity holds the FDA IND or IDE).

For more information about regulatory sponsor status, INDs and IDEs, see the [Penn Manual for Clinical Research, section on Research Involving Drugs or Devices](#).

Name
Type

IND Sponsor Set

This option should be selected when the Principal Investigator, or another Penn faculty member, is the Sponsor of the IND or IDE being referenced for the research.

The Perelman School of Medicine requires that sponsors meet [certain qualifications](#) to serve as a regulatory sponsor (IND/IDE Holder). If the person being selected does not meet these qualifications, please contact the [OCR office](#) for guidance on how to proceed with the application.

Name
Department/School/Division
Phone
Fax
Pager
Email

The project funding question at the bottom of the sponsor page will expand and show additional questions based on your selection:

- If the study is funded by a grant that has a proposal linked to the PI, please select "yes" on the project funding question. Then link the proposal by clicking the "Set" button and upload the grant by clicking the "Upload Form" button. If your proposal is not available please contact the HSERA helpdesk.

- If the study is funded by a grant but the funding contract for the proposal has not yet been finalized through ORS (Office of Research Services), please select Pending for the Project Funding Question. **Please ensure that this is updated via a modification when the funding is finalized.**

- If your study is being funded by an industry sponsor, please select "Yes" under the Project Funding question and select "Yes" under the Sponsor Funding question. Under Status of Contract, please select whether the contract has been completed or is pending.

Industry Sponsor Set

Any additional funding sources not already addressed in the options above, or specific CRO information may be added here. ****This is the billing source for IRB-related fees for industry sponsored research.****

Sponsor Name
Contact Name
Street Address
Street Address (continued)
City, State/Province, Zip/Postal Code
Phone Number
Fax Number
Email Address
CRO Name
CRO Contact Person
CRO Street Address
CRO Street Address (continued)
CRO City, State/Province, Zip/Postal Code
CRO Phone
CRO Fax
CRO Email
Send bills for IRB to

Clicking the green "Set" button will allow you to fill in the blanks in the section shown in the shaded box below. After you click "Save" you will be directed back to the Sponsor page and the information will appear.

Project Funding*

Is this project funded by or associated with a grant or contract?

- Yes
 No
 Pending

[Previous](#) [Next](#) [Save Draft](#)

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Protocol Form - Multi-Center Research

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Site Information

The questions on this page are designed to identify studies that will utilize single IRB review. It is now a common practice for multi-site research studies to seek ethical review and approval of the proposed research by a single IRB. The IRB conducting this review is often referred to as the IRB of Record or Reviewing IRB. The IRBs affiliated with the research sites are then asked to enter into Reliance Agreements or IRB Authorization Agreements and accept the initial and ongoing ethical review and approval of the IRB of Record rather than performing their own separate IRB review and approval. The IRBs that accept the approval of the IRB of Record are referred to as Relying IRBs.

Please note that HUP, Pennsylvania Hospital, Presbyterian Hospital, Chester County Hospital, Lancaster General Hospital and Princeton Medical Center are all considered Penn centers. Research conducted at more than one Penn center is not considered multi-center research. The research will only be considered multi-centered research if additional non-Penn centers are also engaged in the research.

Penn as lead

1. Is this a multi-center study where Penn is serving as the Lead Site or the Penn PI is serving as the Lead Investigator?

- Yes
 No

Management of Information for Multi-center Research where a Penn Investigator is the Lead Investigator of a multi-center study, or Penn is the lead site in a multi-site study. Provide a plan for the management of multi-site information that may be relevant to the protection of human research participants, such as:

- Reporting unanticipated problems involving risks to participants or others.
- Reporting of interim results.
- Coordination of protocol modifications.

Please type your plan into the space provided below or provide a reference to any attached supplemental documents that you have included on the final page of this application.*

Penn irb of record

2. Is this a multi-center study where the Penn IRB will be asked to serve as the IRB of Record for other external study sites?*

- Yes
 No

A. Using the Add button below please identify each of the sites that will rely on the Penn IRB as the IRB of Record. Please note that this list does not have to be complete at the time of initial submission to the IRB. It can be updated in the future via modifications.

Other Sites [Add](#)

B. Management of Lead Study Teams: Please provide your plan for the coordination of study documents among all the

This section is applicable to studies that involve Multi-Center Research, and the Penn Investigator is the Lead Investigator or Penn is the lead site in the management of multi-site information (Data Coordination).

If this section applies to your study, please answer the Management of Information for Multi-Center Research question by entering your response in the text box OR attaching a form with the green upload form button in the middle of the page.

This section is applicable to studies where Penn is serving as the single IRB of Record for external sites. Please enter the other sites affiliated with this study by clicking the green "Add" button.

After you click the "Add" button you will be directed to a page where you can enter in site specific information. Click the save button once you have answered all relevant questions. After you click save you will be directed back to the sites page. Please repeat the steps described above until information for all the study sites has been entered.

--SITES--

After completing the sponsor page, the next page captures studies involving multiple sites.

You may skip the questions on this page if:

- Your study only operates at one site
- Penn researchers are not acting as the lead team or data coordinating team for the other sites involved
- The Penn IRB is not serving as the IRB of record for the other sites involved

PLEASE NOTE:

The Penn IRB oversees all research conducted at Penn Medicine. Studies conducted solely at one or more of Penn Medicine locations are considered a single site study for the purposes of IRB review. You can indicate the hospitals involved on the Basic Info Page.

The rest of the HSERA application beyond the Sites page requires the details of your protocol objectives, design, background, population, procedures, etc.

The IRB highly recommends submission of an IRB standalone protocol instead of relying on the HSERA to serve as your protocol, especially for research requiring expedited or convened review. NOTE: Grant proposals may not serve as an IRB protocol.

If you are submitting an investigator-initiated study and you have not been given a protocol by a sponsor or collaborator, please see the IRB website for templates.

For researchers who already have a prepped Protocol document:

The sections that follow the Sites page can be completed by referencing the appropriate **section of an attached protocol document**. The IRB prefers this instead of typing out or copy/pasting sections of your protocol into the HSERA application. When making references to a protocol document in any section, please be sure to utilize the HSERA space to clearly identify any discrepancies between what the protocol document states and how the study will be conducted at Penn. For example—if the overall study includes a genetic sub-study but participants at Penn will not participate in the sub-study be sure to clearly explain that in the HSERA text field to prevent the IRB from raising unnecessary issues.

--PROTOCOL--

After completing the Sites page, the Protocol page is where specific information about the study objectives, design, duration and resources is required

The first section: Abstract should contain a description of the study.

The next 6 free text sections on this page should be completed with detailed protocol specific information **ONLY** if you are not submitting a protocol document.

Protocol Form - Details of Protocol

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Page must be error free before you can use 'Save Draft'

Abstract*

Brief abstract (250 words or less) describing the study in language understandable to the IRB. Description of the purpose, target disease/condition if applicable, key eligibility criteria.

1

If you have a protocol document to attach, **please copy the abstract in this section**, so the IRB has a general description of the study in this section. If you do not have a protocol document, please consider making one using one of our available templates or fully describe your abstract here.

Objectives

Overall objectives*

Brief statement of the overall objectives of the study

1

If you have a protocol document to attach, **please only reference the section of that document where the Objectives info can be found** (do not copy/paste). If you do not have a protocol document, please consider making one using one of our available templates or fully describe your objectives here.

Primary outcome variable(s)*

Define the primary outcome variable(s) used to support the study objectives. Example: The primary outcome variable is blood pressure measurement.

1

If you have a protocol document to submit, **please only reference the section of that document where the primary outcomes info can be found** (do not copy/paste). If you do not have a protocol document, please consider making one using one of our available templates or fully describe your primary outcomes here.

--PROTOCOL--

The last section on this page about necessary resources to protect participants should always be fully completed with information specific to the study conduct at Penn regardless of the presence of a protocol document.

Design*

Include design issues such as randomized, blinding (double, single, etc), placebo-controlled, parallel group or cross-over, telephone survey, internet research, focus group, etc.

0

Study duration*

List projected overall duration of the study including:

- Estimated length of time to enroll all subjects and complete the study
- Length of a subject's participation time in study
- Project date of the proposed study

0

Resources necessary for human research protection

Describe research staff and justify that the staff are adequate in number and qualifications to conduct the research. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties. Please allow adequate time for the researchers to conduct and complete the research. Please confirm that there are adequate facilities for the research.

0

Protocol Form - Characteristics of the Study Population

Previous Next Save Draft

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If you have a protocol document to attach, **please copy the target population in this section**, so the IRB has a general description in this section. If you do not have a protocol document, please consider making one using one of our available templates or fully describe your abstract here.

Target population*

State the clinical condition, disease state, or diagnosis of Type II diabetes for greater than
Note: Within the limitations imposed by the sufficient enrollment of persons of diverse et research are equitably distributed.

1

This number should show how many participants need to complete the study from beginning to end in order to answer the research question that will be enrolled by Penn affiliated researchers. If your enrollment goals are complex and cannot be defined by one number, please insert zero and fully explain your sample size and enrollment in the "Accrual" section below. This number should include screen failures.

Subjects enrolled by Penn Researchers*

The number of subjects to be recruited at Penn, zero if

1

Subjects enrolled by Collaborating Researchers*

The number of subjects to be recruited at sites other than Penn. Er

Note A multi-center study is a study where different PI's at differ

1

This number should show how many participants need to complete the study from beginning to end in order to answer the research question that will be enrolled by Non-Penn researchers. If this is not a multi site study then this should be Zero

Accrual*

Explain how you will have access to a population that will allow you to recruit the required number of subjects. Describe the statistical methods or theoretical justification for determining sample size or sampling approach for the study.

1

The accrual section should describe how your study team will access the targeted population and justify your sample size. Additionally, if you anticipate that a significant number of consented participants will not qualify for participation or that participant retention may be an issue, please explain that here. For example "Although our sample size is 40 participants we will likely have to consent and screen 150 – 200 participants in order to reach this goal due to the strict eligibility and screening requirements."

--POPULATIONS --

The next page of the application is related to your targeted populations.

The Populations page has been divided into 4 slides to capture all of the questions

Part 1: Target population and sample size

--POPULATIONS --

Part 2: Inclusion and Exclusion + vulnerable populations by regulatory definitions

Key inclusion criteria*

List key inclusion criteria including age range

1

If you have a protocol document to attach, **please only reference the section of that document where the inclusion criteria info can be found** (do not copy/paste). If you do not have a protocol document, please consider making one using one of our available templates or fully describe your inclusion criteria here.

Key exclusion criteria*

List key exclusion criteria. If subjects are excluded, provide justification for exclusion.

1

If you have a protocol document to submit, **please only reference the section of that document where the exclusion criteria info can be found** (do not copy/paste). If you do not have a protocol document, please consider making one using one of our available templates or fully describe your exclusion criteria here.

Vulnerable Populations*

Specify if the study intentionally includes any of the following populations:

Note: Include the appropriate supplemental form for each vulnerable population included in the study.

Note: Subjects who become imprisoned or are court-ordered to attend residential alcohol or other drug treatment facilities will be considered prisoners under Subpart C of the federal regulations 45CFR46. Such subjects cannot be continued in the research unless an amendment to the protocol is submitted and approved by the IRB and certification to the federal Office of Human Research Protections if the research is supported by the Department of Health and Human services.

- Children [Form](#)
- Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) [Form](#)
- Fetuses and/or Neonates [Form](#)
- Prisoners [Form](#)
- Other
- None of the above populations are included in the study

There are no documents attached for this item.

[Upload form](#)

Certain populations are designated as “vulnerable” by the human research protections regulations. If your study involves the participation of these populations, your study may require additional protections for these participants. Please identify them by checking the appropriate boxes and attach a completed copy of the related supplemental form that is required for each population.

-- POPULATIONS --

Part 3: Other Vulnerable Populations and Recruitment

The participant recruitment section should always be fully completed with information specific to the study conduct at Penn regardless of the presence of a protocol document.

Populations vulnerable to undue influence or coercion*

When some or all of the participants were likely to be vulnerable to coercion or undue influence or influence such as mentally disabled persons, or economically disadvantaged persons, employees or students of Penn describe the additional safeguards have been included in the study to protect the rights and welfare of these subjects from coercion or undue influence.

Note: This section is intended to elicit information regarding additional protections when specific populations are included in a research study. It is not intended to trigger an exclusion of these populations.

0

Please read these instructions carefully before responding. This question is required for approval and your answer may dictate additional language for your consent process. Please be sure to note that any Penn affiliates will be told that their decision will not affect their standing with the University. Also, you don't need to reiterate any groups from the vulnerable populations section.

Participant recruitment*

Please describe the plan to **equitably** identify and recruit a diverse group of participants that is reflective of the population under study. If this is a multicenter protocol, the recruitment plan should describe the local (Penn) site's plan. Describe:

- how potential participants may be identified (review of medical records, Slicer Dicer, DAC reports including referrals from physician offices and clinics);
- who may approach potential participants;
- methods to achieve sample diversity and inclusiveness;
- what information may be presented to or discussed with them; and
- the context and setting in which recruitment will happen.

0

Please ensure that your recruitment plan aligns with Penn guidance: <https://irb.upenn.edu/homepage/biomedical-homepage/guidance/recruitment-and-consent/recruitment-of-human-participants>. Ensure the plan also covers any use of recruitment materials.

-- POPULATIONS --

Part 3: Other Vulnerable Populations and Recruitment

All recruitment materials must be IRB approved prior to use.

Recruitment Materials*

Is the research team using any recruitment materials? These may include but are not limited to: phone call scripts, radio/video scripts, flyers/brochures, internet postings, email, letters to potential participants, letters to patient physicians, My Penn Medicine (MPM), other direct messaging, etc. For guidance regarding recruitment materials, please review the IRB's guidance on Participant Recruitment Materials online:

<https://irb.upenn.edu/recruitment>

- Yes
- No

Use the following button to upload sample **recruitment materials** (i.e. radio/video scripts, flyers, internet postings, etc.) For guidance regarding recruitment materials, please see the following link:

<https://irb.upenn.edu/recruitment>

NOTE: Please upload all
There are no documents

Click the "upload form" button to attach your flyers, posters, scripts, and other recruitment materials.

Upload form

-- POPULATIONS --

Part 4: Internet recruitment

Use of Penn Media & Social Media Services*

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?

- Yes
 No

Please indicate whether social media or the internet will be used to recruit participants. Guidance about use of social media in research is available on the IRB website.

Please identify which method(s) of social media you will utilize, the content of the text to be used, and the method(s) for posting this information (i.e., using Penn supported communication services). When proposing the text to utilize, please be aware of any social media limitations (i.e., number of characters allowed in a tweet) and any appropriate confidentiality practices necessary to be compliant with posting research recruitment text.

NOTE: Penn Medicine must utilize one of the centralized PM Facebook Pages:

- ClinicalResearch@Penn Facebook page
- Penn Medicine Facebook page
- @PennCancer Facebook page

All clinical research paid Facebook ads must be listed on Clinical Research @ Penn Facebook page, www.facebook.com/ClinicalTrialsAtPenn.

Exceptions to the above must get approval from the Penn Medicine Social Media Committee: pennmedicinesocialmediacommittee@uphs.upenn.edu.*

If the plan for online recruitment is fully outlined in your protocol document please only include a reference to the applicable section. Otherwise, please detail your plan for the online recruitment strategies including; the names of sites, the plan for publishing and managing online content, confidentiality etc.

-- POPULATIONS --
Part 5: Participant
compensation

Subject compensation*

Will subjects be financially compensated for their participation?

- Yes
 No

Please indicate whether participants will be compensated in any way for participation.

Summarize any financial compensation that will be offered to subjects, e.g. Greenphire ClinCard, cash payments, gift card, reimbursement for travel. The amount of compensation may not constitute an undue inducement to participate in the research. A prorated system of financial compensation is required in most circumstances. Provide the schedule for compensation per study visit or session and total amount for entire participation.

0

If the plan for compensation is fully outlined in your protocol document, **please only include a reference to the applicable section here**. Otherwise please fully detail the compensation plan including; total amount a participant may receive, amounts received per study interaction, form of compensation. Compensation must also be fully outlined during the consent process.

There are no documents

Upload form

-- PROCEDURES--

After completing the Populations page, on the next page you will detail the procedures, statistical analysis, and data security methods for your study.

The procedures page is the longest part of the application. The following slides will cover select parts of this Procedures section.

Sections included on the Procedures Page

- Use of a drug that may affect the Central Nervous System
- Full description of procedures
- Use of deception
- International Research
- Analysis Plan
- Confidentiality
- Sensitive Research Information
- Subject Privacy
- Data Disclosure
- Protected Health Information
- Limited Datasets
- Tissue/Specimens Information
- Genetic Testing

Tips for completion

- As you complete the questions on this page, additional questions may populate depending on your response to the trigger questions.
- Any section on this page that is a free text box can be completed with a reference to the appropriate section of your protocol document. If you do not have a protocol document please fully explain each response in the space provided
- When making references to your attached protocol, please be sure to clarify any information in the protocol that may be different for the Penn site (for example if participants at Penn will not have a particular MRI scan, or sub study blood draw please clearly state that in the HSERA text box)
- Any checkboxes or radial buttons must be completed accurately regardless of whether the information is included in an attached protocol

-- PROCEDURES--

Analysis plan: This section should cover the statistical analysis of the data.

Data Confidentiality: Please check off the data confidentiality measures that apply to your study.

Analysis Plan*

Describe briefly the statistical methods used to analyze the data

- **Note:** If the statistical methods used are described in the detailed protocol, this section may reference the detailed protocol.

0

If the plan for data analysis is fully outlined in your protocol document, please only **include a reference to the applicable section here**. Otherwise please fully detail the analysis plan. **Having a plan for statistical analysis prior to conducting the research ensures bias is minimized in the results.**

There are no documents attached for this item.

Upload form

Data confidentiality

Confidentiality refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared.

How will confidentiality of data be maintained? Check all that apply

- Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.
- Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.
- Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.
- Wherever feasible, identifiers will be removed from study-related information.
- A Certificate of Confidentiality will be obtained, because the research could place the subject at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or liability.
- A waiver of documentation of consent is being requested, because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality. (This is not an option for FDA-regulated research.)
- Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.
- Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.

-- PROCEDURES--

Privacy and Confidentiality of data

These sections should always be fully completed with information specific to the study conduct at Penn regardless of the presence of a protocol document.

Subject Confidentiality*

Confidentiality refers to the researcher's agreement with the participant about how the participant's identifiable private information will be handled, managed, and disseminated. The research proposal should outline strategies to maintain confidentiality of identifiable data, including controls on storage, handling, and sharing of data. When developing strategies for the protection of subjects' confidentiality, consideration will be given as to:

- Methods to shield participants' identity adequately protect participant privacy.

The long-range plan for protecting the confidentiality of data.

Your Confidentiality plan should outline a local plan for how you will keep participant information confidential after it has been documented, abstracted, or recorded. This includes plans for secure storage and sharing of PHI.

PHI is Protected Health Information. Most PHI and study data is recorded electronically. Implementation of a University vetted plan to protect electronic research data (storage and sharing) became required in August 2016. Please see <https://irb.upenn.edu/homepage/biomedical-homepage/guidance/research-with-penn-patients/hipaa-in-research/> guidance on the IRB website to assist investigators in developing an appropriate electronic PHI / data protection plan in collaboration with local IT support providers.

Subject Privacy*

Privacy refers to the person's desire to control access of others to themselves. Privacy concerns people, whereas confidentiality concerns data. Describe the strategies to protect privacy giving consideration to the following:

- The degree to which privacy can be expected in the proposed research and the safeguards that will be put into place to respect those boundaries.
- The methods used to identify and contact potential participants.
- The settings in which an individual will be interacting with an investigator.
- The privacy guidelines developed by relevant professions, professional associations and scholarly disciplines (e.g., psychiatry, genetic counseling, oral history, anthropology, psychology).

Your Privacy plan should outline how you will make each face to face, telephone, or online interaction with participants as private as possible. This section is not asking about HIPAA privacy.

-- PROCEDURES--

Data/Specimen Disclosures and Protected Health Information (PHI) Identifiers

Disclosures*

Will any data or specimens from Penn participants OR other research generated work product (e.g., intellectual property) be disclosed to any individuals, entities, or vendors, etc. outside of Penn?

- Yes
 No

Identify individuals and/or entities by name. A contract or agreement is required to be executed for all disclosures outside of Penn. Please reach out to the appropriate contracting unit for agreement execution.*

This section should detail any entities or individuals to which data or specimens may be disclosed, outside of Penn.

Protected Health Information/Data Protection*

Describe if data to be used or collected involves any protected health information (PHI) and specify which PHI is to be used/collected. Health information is determined to be PHI if it contains any of the following identifiers:

- Name
- Street address, city, county, precinct, zip code, and equivalent geocodes
- All elements of dates (except year) for dates directly related to an individual and all ages over 89
- Telephone and fax number
- Electronic mail addresses
- Social security numbers
- Medical record numbers
- Health plan ID numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers
- Device identifiers/serial numbers
- Web addresses (URLs)
- Internet IP addresses
- Biometric identifiers, incl. finger and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic, or code
- None

All identifiers that may be accessed (used), collected, or shared for the purposes of the research should be checked here.

If obtaining informed consent, please ensure the list of identifiers in the consent matches this list, or the IRB may require changes.

Basic Info	Personnel	Bio	Sponsors	Sites	Protocol	Populations	Procedures
------------	-----------	-----	----------	-------	----------	-------------	------------

Protocol Form - Consent

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1. Consent Process

Overview*
 Summarize how informed consent will be obtained, including how, when, where, and by whom it will be obtained. Describe any waiting period between informing the prospective participant and obtaining the consent. Describe any steps taken to minimize the possibility of coercion or undue influence. Describe the language used by those obtaining consent. Describe the language understood by the prospective participant or the legally authorized representative.

Please indicate who will provide consent or permission if the subject is incapable. Additionally, please describe the information to be communicated to the prospective participant or the legally authorized representative.

Informed consent is an ongoing process that takes place between the investigator/study staff and study participants. In most cases, this process is initiated with written informed consent at the start of the study; however, it also takes place as an ongoing dialogue between the investigator/study staff and subjects during the entire duration of their participation.

Children and Adolescents*
 If children or adolescents are enrolled, describe the consent process including parental permission and subject assent. Please note: Except for research involving no greater than minimal risk, if a court appointed guardian provides consent, documentation of the court order or legal authorization to consent to general medical care must be copied and included in the investigator's research records with the documentation of permission.

Adult Subjects Not Competent to Give Consent* ←
 Will all adult subjects be competent to give informed consent? If not, respond to the following:

- What is the likely degree of impairment? How will competency be assessed (eg, informal assessment by the investigator, mini-mental status exam, formal psychiatric evaluation)?
Note: *The methods of assessment of competence should be based on the population to be studied and the likelihood of cognitive or decisional impairment in that population.*
- Will consent be obtained from a legally authorized representative, from whom will consent be obtained? Refer to the IRB Policy 705, Surrogate Consent/Authorization for guidance.
- Will subject assent be obtained? If no, provide justification.
Note: *Respect for persons requires that assent (or at least lack of active dissent) be obtained in most cases.*

This section should detail any specialized consent procedures or resources in place for participants who may participate but are unable to complete a traditional consent process noted in the overview section. Such as:

- Blindness or other visual impairment
- Deafness or other hearing impairment
- Short term or permanent cognitive impairment
- Short term or permanent physical limitations

Please note that predicting all possible scenarios is not required. If necessity for a specialized consent process is identified in the future, the IRB may approve the plan via submission of an exception request

--CONSENT--

After completing sections about procedures, you must describe the consent process. If this information is fully detailed in your protocol please only include references to the applicable sections. Please see: <https://irb.upenn.edu/informed-consent/> for guidance

When making references to the protocol document please be sure to clarify any differences for how consent will be obtained at the Penn site.

For example if the protocol includes an assent and parental permission section but Children will not be on the study at Penn, the children and adolescent section should state "Children will not be enrolled at Penn"

--CONSENT--

The final question on the Consent page is related to waivers of consent.

If you indicate on this page that you are requesting any type of waiver, additional required questions will populate.

If you are not requesting a waiver of consent, please select "No Waiver Requested"

Please see <https://irb.upenn.edu/homepage/bio-medical-homepage/guidance/recruitment-and-consent/waivers-of-consent/> for guidance

Waiver or Alteration of required elements of consent

- Requesting this type of waiver means you do not intend to ask participants to be part of your protocol (waiver) or are withholding information from them (deception/incomplete disclosure).
- A waiver is often requested for retrospective review of existing medical records
- If you plan to waive consent, you may also need to include a request for Waiver of HIPAA authorization (see IRB Forms website page) for use of health information, if applicable.

Waiver of Documentation of consent

- Requesting this type of waiver means you WILL ask participants to be part of your study, but they will not physically sign their name to a document.
- Typically, this is requested for online surveys where participants click "I agree to participate" OR for telephone surveys where verbal consent is obtained.
- Occasionally participants would only be identified by their signature on a form which may increase risk to the participant.

--Risk/Benefit --

After describing the consent process, the application requires an assessment of risk to participants and potential benefits of participation.

If your protocol document fully discusses the topics on this page **please make references to the applicable sections** (do not copy/paste)

This page also requires description of the Data and Safety monitoring plan. This plan will be referenced during annual continuing review (if applicable) to ensure adherence to the plan throughout the life of the study.

Protocol Form - Risk / Benefit

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Page must be error free before you can use 'Save Draft'

Potential Study Risks*

Describe and assess any potential risks associated with the research interventions (physical, psychological, social, economic, monetary, legal or other, loss of confidentiality) and assess the likelihood and seriousness of such risks. If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used.

1

Potential Study Benefits*

Assess the potential benefits to be gained by the individual subject, as well as benefits that may accrue to society in general as a result of the planned work (such as advancement of knowledge). Summary should also state if there are no direct benefits to subjects as a result of their participation in the study.

1

Alternatives to Participation (optional)

Describe the alternatives available to the subject outside the research context.

1

The alternatives section is optional when the only alternative to participation is not participating. Otherwise, a full description of existing standard options must be included

Protocol Form - Submitter's assurance

Documents attached within the application

This section will show you any documents that you attached on previous pages

Additional forms or documents

Check all that apply

Cover Letter (with additional information that may help in the review)
There are no documents attached for this item.

Upload form

To add more documents please check the box next to the type of document you would like to attach and use the green "upload form" button to attach your files.

Full sponsor's protocol
Please note: If you do not have a full/clinical protocol for upload, and are using developed templates for common types of human subjects' research submit a cover letter.
There are no documents attached for this item.

Upload form

Please be mindful to attach each document under the most appropriate header to assist the IRB in identifying your documents. You can attach as many documents as you need.

Grant Application (minus the appendices & budget information, for federal grants)

Performance site approvals for sites other than Penn (this does not apply to Penn sites)

Informed consent form (and parental permission/assent form for research involving children)

HIPAA Authorization or Waiver (if applicable)

Investigator's brochure/product labeling (for research involving investigational drugs or devices)

Please note that your cover letter should include a list of all documents being submitted for review

Supporting documents

Check all that apply

Supplemental form(s) for research involving pregnant women, fetuses, neonates, prisoners, or children

Questionnaires, inventories surveys, diaries, personality tests, quality of life assessment or other surveys or inventories, data collection forms to be completed by subjects, interview & focus group scripts, consent and recruitment scripts.

Exception: Widely recognized, accepted, standard tests in a given field do not need to be submitted for review.

All recruitment materials, including advertisements, brochures, letters to patients, transcripts of all broadcast materials, etc, if available. Otherwise submit when available for expedited review.

If you have additional forms or documents to attach to this protocol, please attach them here.

When you are done filling out the application and have attached all your documents you must click the "I accept" button to send in your submission.

By clicking "I accept" below, you are electronically signing the following:

I have read and understood the University of Pennsylvania guidelines concerning human subjects projects and protocols.

I certify that the information provided in this submission is complete and correct to the best of my knowledge.

[Back](#) [I accept](#)

--CONFIRMATION--

The confirmation page is the final page of the application where you will attach any necessary documents that you have not already attached.

If you have already attached a document in another part of the application, you do not have to re-attach it here again.

What happens after you click "I Accept"..?

Request Has Been Submitted

Thank you for submitting to the Institutional Review Board (IRB).

A confirmation of your submission has been sent to you at your email address on file.

Confirmation# **bci2ib**

Principal Investigator: STANKO, PATRICK A

Title: my training protocol

[Next](#)

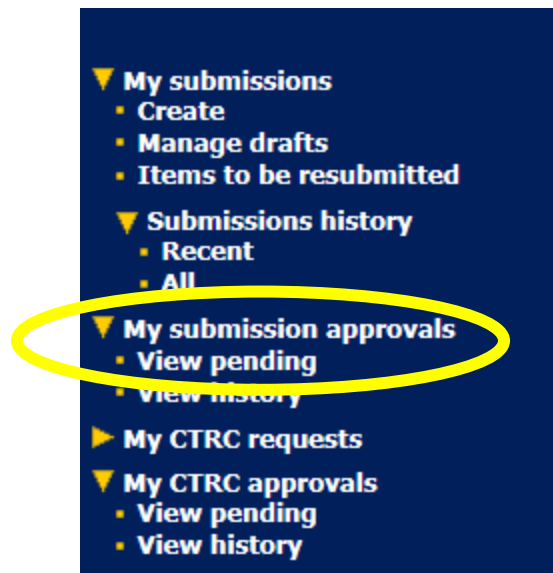
Immediately after clicking "I Accept" you will be shown a screen that provides a confirmation code. You should save the confirmation codes for every submission you create in the system

- The IRB will rely on this code to find your submission in the system. Please include it in all email correspondence or have it ready before you call on the telephone
- You will need the code to locate your decision letter in the system once it is uploaded by the IRB staff. The code associated with each submission is included in the IRB determination letter for that submission
- If you ever need to refer back to your original application in the future, you will need the code to locate it in your "Submission History"

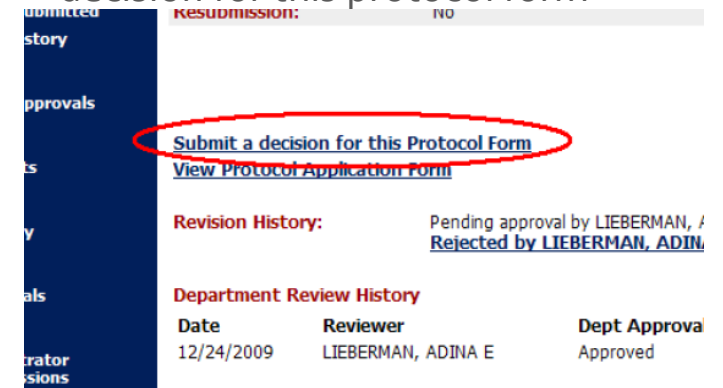
What happens after you click "I Accept"...

Clicking "I Accept" on an initial submission does not mean the IRB can begin its review.

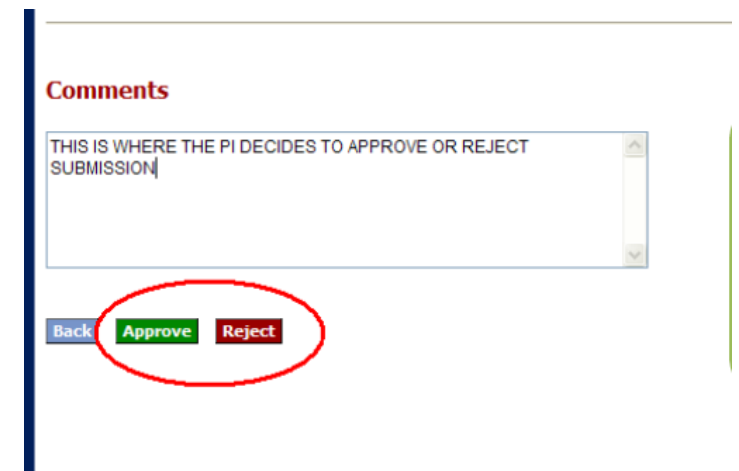
- If the submitter of the initial application is not the PI, the submission then requires PI approval. The PI will receive an automated email alerting them of the pending submission. The PI can access the application by clicking "View Pending" under "My Submission Approvals" on the blue left side menu in HSERA



- Once the submission is identified and chosen in the "view pending" list, the PI must click "submit a decision for this protocol form"

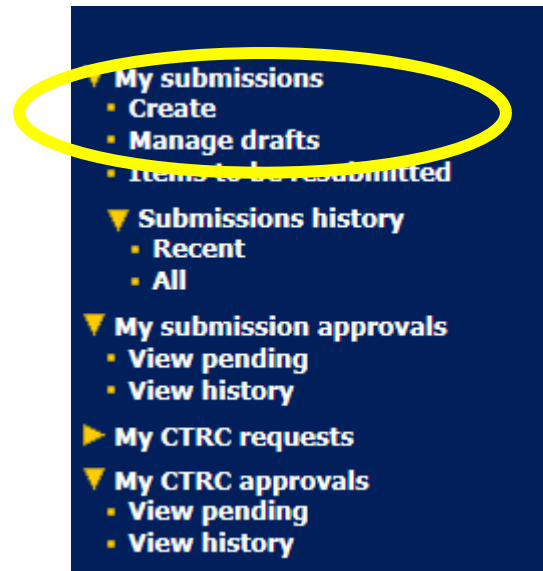


and on the last page of the application, choose to either approve or reject it



What happens after the PI approves it?

- If the PI identified any issues with the application and decides to reject it, the submission will be available to the study team in the “manage drafts” . Searching on this page by confirmation code is the fastest way to find the submission.



- Once the PI approves the submission it then requires approval by the department head. The department head who is charged with approving the submission is determined by the “ORG code” that was chosen on the Personnel page
- The department head follows the same steps as the PI to approve the submission and may also reject the submission for any reason
- After the department head approves the submission, the IRB receives it in the system to begin its review.
- Departmental approval is only required for submission of the first draft of an Initial submission. All future submissions require only PI approval

Members of the study team can check the status of any submission by looking in "Submission History" and sorting by the available search fields



IRB Submission

Welcome
WIRTANEN, EMILY A

- ▼ My submissions
 - Create
 - Manage drafts
 - Items to be resubmitted
- ▼ **Submissions history**
 - Recent
 - All
- ▼ My submission approvals
 - View pending
 - View history
- ▼ My CTRC requests
 - Create

All Submissions

All submissions created using this system

Confirmation #

Protocol #

Principal Investigator None

Title starts with

Click on any column heading to sort by that column

If a submission is pending review by a person (PI or Dept. Head) that person's name will be displayed in the "Status" column

Type	Principal Investigator	Submission Date	Title	Status	
Reportable Event	ZIOLEK, TRACY A		IRB QA Protocol	Draft	
Protocol	WIRTANEN, EMILY A		1	Draft	
Protocol				Draft	
Protocol	ZIOLEK, TRACY A		132	Draft	
Protocol	ZIOLEK, TRACY A	07/31/2015	IRB QA Protocol	Assigned to IRB #5	

Click here to delete but be careful!

Click here to view

Click here to edit

Summary of submission process

If you have begun the process and have questions that cannot be answered by this walkthrough, please send a detailed email to an IRB staff member.

Various contacts are available on the IRB website

- **Step 1:** Submission is drafted.
- **Step 2:** PI reviews and approves the study. (submission may be returned for revision)
- **Step 3:** Department Chair reviews and approves the study. (submission may be returned for revision)
- **Step 4:** IRB pre-screen for initial review. (submission may be returned for revision)
- **Step 5:** IRB Review is scheduled. Protocol number and IRB Board number assigned.
- **Step 6:** IRB Review. Submissions requiring full board review will likely be returned for revisions prior to receiving full approval.
- **Step 7:** Resubmission of protocol to meet IRB stipulations.
- **Step 8:** Final IRB Review and approval.