Penn
University of Pennsylvania
Human Research Protections Program

Student Guidance Manual: Submitting to the Penn IRB

Students should thoroughly review this guidance document and follow up with the IRB staff regarding any follow up questions they may have.

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When should I start the IRB process?

IRB review is required before research can commence. Therefore, it is **critical** that you ensure you have allowed enough time for the IRB process. You will need to allow time for the following:

1. Determining whether your study requires IRB review;
2. Completing any required trainings (e.g., CITI training);
3. Drafting your IRB application and associated study documents;
4. Completing any revisions from your advisor and/or department chair;
5. The initial IRB review process;
6. Completing any revisions required by the IRB;
7. IRB review and approval of your responses;
8. Obtaining any other supplemental approvals that may be necessary.

Given all of these steps, the IRB recommends that students begin this process 2-3 months before they plan to commence their research. Hence, it would be best practice for the above steps to commence the semester prior to commencing research to ensure that the process is not stressful and rushed.

Step 1: Determining whether your study requires IRB review

Not all research requires IRB review. Only activities that meet the definition of human subjects' research as outlined in federal regulations require IRB review.

What is research?

The Department of Health and Human Services' (DHHS) regulations define research as: "A *systematic investigation*, including research development, testing and evaluation, *designed* to develop or *contribute* to *generalizable knowledge*."

What is a human subject?

DHHS regulations also define a human subject as: "A living individual, about whom an investigator conducting research obtains:
(1) Data through intervention or interaction with the individual, OR
(2) Identifiable private information."

Some endeavors do not meet the *regulatory* criteria for research and/or do not involve human subjects. This may include activities such as but not limited to: **quality / performance improvement** activities and **journalistic activities** (oral history, journalism, biography, literary criticism, legal research, or historical scholarship).

> **If you think your project may not meet the regulatory criteria for human subjects research, you can complete the Human Subjects Research Determination Form available online here: https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/types-research. Fill out the form and submit it to one of the contacts listed on the IRB webpage.**

If you think your project may fall under quality / performance improvement activities, please review the IRB guidance on these activities: https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/quality-performance-improvement-project-guidance.

If you need help determining whether your project meets the criteria for QI/PI, please follow the steps for submission outlined on the IRB webpage linked above.

Step 2: Completing any required trainings

Once you have confirmed that IRB review is required, you should make sure that you have completed any trainings required by the IRB, your school, and/or department/ division.

The **IRB required training is the CITI *Human Research* curriculum.** Details about this are outlined online here: https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/citi-training. This training is only required for projects that meet the regulatory criteria for human subjects' research.

If the activity is not part of a class you are enrolled in, you should select either the Biomedical Research or Social/Behavioral Research learner group.

Step 3: Drafting your IRB application & Associated Study Documents

A. Review Relevant Guidance

Before or while you are drafting the application and study documents, you should review any guidance information that is relevant to your research.

Applicable to all submissions:

- **How to Submit**: Detailed guidance on how to submit to the Penn IRB is online here: https://irb.upenn.edu/initial. This webpage includes a detailed walk-through of submitting in HS-ERA, which is the IRB's online application submission system.
- HSERA Help: This webpage includes FAQs about HSERA.

Other Guidance

- Guidance for Using MTurk for Research Purposes: Please review if you are utilizing MTurk.
- Social Media Guidance Document: Please review if you are using social media as part of your research.
- Subject Recruitment Materials, Subject Compensation, Recruitment Finders Fees / Bonuses: Guidance on what should be included in recruitment materials, ethical considerations around compensation, etc.

- Guidance on Remote Consent Procedures: Please review if you may need to conduct a virtual consent process.
- **International Research**: For those engaging in human subjects' research in other countries:
  - You are responsible for reviewing DHHS's International Compilation of Human Research Standards to determine what international regulations you may be required to follow. This document contains links to human subject regulations and standards in various countries.
  - You should also familiarize yourself with any local laws and /or cultural customs.
  - Depending on the country where you will be conducting a study, your target population, and study design, you may or may not need to obtain local IRB or ethics approval. Many institutions have ethics committees that review research. *The IRB strongly recommends having a research collaborator in the country in which you plan to conduct research to facilitate any necessary ethical committee reviews.*

B. Draft the Online Application

Don't stress over selecting the review level (exempt, expedited, or full) nor the exempt or expedited category your research falls under. The IRB makes the final decision as to whether the study qualifies for exemption or expedited review under the pre-defined categories. *If in doubt, select the expedited application* by responding that none of the exempt categories apply.

Tips for completing HSERA include:

If you have a standalone IRB protocol, you should upload this into HSERA prior to your submission of the application. If you do not have a standalone protocol, the HSERA application serves as your IRB protocol. Theses and dissertations may not serve as an IRB protocol, but may be uploaded as a reference document.

What to Cover in an IRB Application

The IRB determines whether research can be approved based on the criteria for approval outlined in the federal regulations. These are outlined below. You should articulate in your IRB application how these criteria with rationale.

Risks to subjects are minimized, & reasonable in relation to benefits	Subject selection is equitable	Participant privacy is protected
•Describe the potential risks. Risks may be physical, psychological, reputational, economic, social etc. •Describe the elements in place to mitigate these risks	•Inclusion of participants is fair •There is rationale for the inclusion or exclusion of certain populations	•Describe how physical privacy of participants be ensured? (e.g., reserach will take place in a private location)

Confidentiality of data is protected	Consent will be sought / documented	There are safeguards for vulnerable subjects
•Describe how the data will be protected and secured. •It is best practice to remove identifiers whenever possible and to save data on an institution's IT protected server	•Describe the consent process (discussion with participants) •If consent will not be obtained, provide rationale for a waiver.	•As applicable •Describe the procedures in place to protect autonomy of these participants. See section below for more considerations.

C. Complete Required Supplemental Application Forms

Some research requires supplemental forms, which are online here: https://irb.upenn.edu/forms. These forms should be uploaded in HSERA prior to your submission of the application.

These forms include, but are not limited to:

- Vulnerable Populations Forms: The federal regulations officially define three vulnerable populations. Research involving the following vulnerable populations require supplemental forms: children, pregnant women, or prisoners because there are additional regulatory protections in place for these three groups.

  Also, consider whether your research targets any other vulnerable populations, i.e., those who may be vulnerable to coercion or undue influence to participate. This may include individuals who are economically disadvantaged, homeless, elderly, mentally disabled or otherwise cognitively impaired, patients with stigmatic diseases (e.g., HIV, psychiatric conditions), undocumented immigrants or refugees, LGBTQ, persons of color, students, employees, non-English speaking subjects, and others.

  The researcher should consider what additional provisions may be needed to ensure participant autonomy and to protect these subjects, their privacy and confidentiality of their data. This should be described in the IRB application.

- Community Based Research: Submit this supplemental form when your research involves conducting research procedures at community sites external to Penn (e.g., public places, community centers, shelters, places of worship, etc.). A community site may be local to the Philadelphia area or it may be applicable to a community in a foreign country.

- Request for Waiver of HIPAA Authorization: If you require access to protected health information but are not able to obtain prospective consent and HIPAA authorization. This will generally apply only to students within Penn Dental, Penn Medicine, or School of Nursing.

D. Draft Associated Study Documents

Start with template documents to facilitate IRB review. These are online here: https://irb.upenn.edu/forms. You may revise them as needed.

Materials that will be provided to, presented to, and/or read to the participants are required to be submitted to the IRB for review, including:

- Consent scripts/forms,
- Advertisements / brochures / flyers,
- Interview scripts,
- Educational materials,
- Other audiovisual materials

Use simple language in your participant materials and remember that these are professional documents representing you and the University. Consider the education level of your participants. If you are working with a heterogenous participant pool, it is generally recommended that participant materials be understandable to those with a 7th grade reading level. If you are working with a highly educated group of participants, a higher reading level of materials may be acceptable. Review the IRB's Literacy Guidance for additional guidance: https://irb.upenn.edu/sites/default/files/Health%20Literacy%20Guidance.pdf.

Tests/ assessments/ surveys/ questionnaires that are created explicitly for the current study should be provided for IRB review. Validated, published tests/ assessments/ constructs **do not** need to be uploaded, but can be described and referenced in the HSERA application.

Consent Considerations

The following graphic outlines various consent options based on the type of research being conducted.

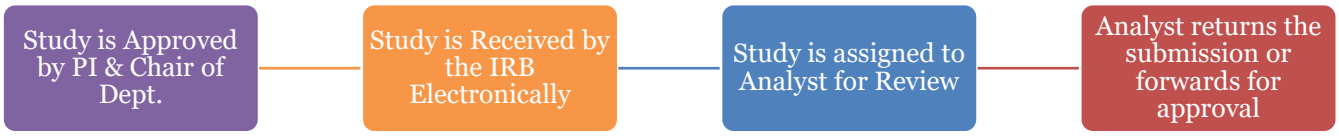
Full Informed Consent	•Administering an intervention •Collection of sensitive information
Alteration of Informed Consent	•When interventions implemented across a whole institution, participants are given option to opt out
Waiver of Documentation	•Waives the requirement for signature •Appropriate for Interviews, Surveys, Questionnaires
Full Waiver	•Retrospective review of administrative records

Step 4: Completing any revisions from your advisor and/or department chair

Before your study is received by the IRB, your faculty advisor (listed as the principal investigator) must review and approve the submission. After this, the department chair will review and approve the submission in HSERA. Your faculty and department chair are responsible for determining the scientific and scholarly validity of your study. Certain sections of the protocol templates or online application should be geared toward the scientific/scholarly review such as the background, study rationale, methodology, etc. The faculty advisor and department chair may return the submission for revisions. You should make the requested changes and resubmit.

Step 5: The Initial IRB Review Process

After Department Chair approval is provided in the system, the IRB receives the submission. The IRB will assign your submission to an analyst. The analyst will review the submission and return it to you in HSERA for required revisions, or they will email you. Notifications from HSERA are sent to your email as displayed in HSERA.



Step 6: Completing any revisions required by the IRB

Review guidance on How to Respond to the IRB: https://irb.upenn.edu/responding. Draft your response and revisions to the documents. Ensure that you track the changes that you make to your study documents. The IRB application automatically tracks changes made. Then resubmit the study in HSERA.

Step 7: IRB review and approval of your responses

The IRB will review your responses and determine if they are acceptable. If they are not, or there are additional questions, the IRB will email you or return the submission again in HSERA. If the response are acceptable, the study will be forwarded for approval and letter drafting. Your letter will be uploaded into HSERA. You may not receive a notification if the study is exempt, so you should check HSERA for the letter before contacting the IRB staff.

Step 8 (if applicable): Obtaining other supplemental approvals

If your research involves conducting research at a site outside of Penn or in another country, you may have to obtain approval to conduct your research at those sites. In these cases, the IRB may ask for a letter of support and/or international ethics committee approval before giving full approval.

Frequently Asked Questions

Q: If the study is determined not to be human subjects' research, can I still publish?
A: Yes. The intent to publish the results of a project does not determine whether or not it needs IRB review.

Q: Who can serve as a Principal Investigator?
A: Per Penn policies, students or trainees (e.g. residents) cannot serve as PI on their graduate thesis /dissertation projects.

Q: What is considered sensitive information?
A: Any information that would put an individual at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

Q: Can researchers' audio or video record interviews?
A: Yes, but you must inform the interviewees that you will be recording the conversation and ask for their permission. You must also inform them your plan to protect the recorded data and any plans to destroy it or de-identify it. If you will be using a transcription company, you should upload the company's privacy/confidentiality policy.

Who to Contact?

- For **general IRB inquiries**, including status of review progress, questions, concerns or complaints regarding IRB review contact PROVOST-IRB@pobox.upenn.edu
- For **technical issues** with the online submission system, contact the HSERA Help Desk @ hsera_help@lists.upenn.edu
- For **issues obtaining or documenting CITI training** contact the CITI Training Help Desk @ IRBCITISupport@lists.upenn.edu
- For other inquiries that do not fall under the categories above, contact anyone with "Analyst" in their title from the IRB Staff Directory: https://irb.upenn.edu/directory.