Minimal Risk Research IRB FAQ

Quality Improvement/Not Human Subjects Research

Q: Do QI Projects need IRB review?
   - If the project is designed to contribute to generalizable knowledge, IRB review is needed. If it’s focused on improving a local setting, IRB review is not needed.
   - Please also refer to the QI guidance on the IRB website which discusses this in further detail.

Q: What are QI projects that don’t need IRB review?
   - Mostly department-specific projects that are being conducted to improve patient care or internal workflow.

Q: How do researchers submit applications that may qualify as QI?
   - Quality improvement projects should be submitted using a separate QI application available on the Penn IRB website → email to qiiirb@upenn.edu

Q: Does the IRB have to decide what is QI?
   - No. Investigators and departments can determine when IRB review is not required. IRB is here to help when you are not sure.

Q: Can I still publish my findings?
   - Yes. The intent to publish the results of a project does not determine whether or not it needs IRB review. The publication should not refer to the activity as research and should make it clear that the publication is the result of a quality improvement activity.

Q: What if researcher has external funding for my project?
   - If a project is funded by an external research grant, it should be submitted for IRB review.

Q: What are other projects that do not require IRB review?
   - Projects that use publicly available data
   - Projects that use fully de-identified data
   - Project that do not obtain information about an individual human subject
   - Student projects that do not contribute to generalizable knowledge

Q: What does de-identified mean?
   - Data that has had all direct and indirect identifiable information permanently removed. If data is coded, no one using the data can have access to the linking set for the code.
Q: What is exempt category 1?
   - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on effectiveness of or comparison among instructional techniques, curricula, and classroom management methods.

Q: What is considered a normal educational practice or setting?
   - A practice or setting that is not manipulated by the investigator.

Q: What does the IRB need to know?
   - What information is collected?
   - How is it collected?
   - Are children involved in the study?
   - Are consent obtained?
   - How is consent obtained? – copy of consent form/script

Q: Do I need review by the City/School District’s IRB?
   - If researchers will be going to the school property and interacting with either the school staff and/or students, most likely they will need their IRB approval. Check their website for detailed information on their review process and policies.

Q: Do I need permission from the school?
   - Yes. Please provide documentation of permission from the school.

Q: What is exempt category 2?
   - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
Q: Can I collect identifiable information and still be exempt?

- Sometimes. If the information is not sensitive, you can collect identifiable information and be exempt. If the information is sensitive, you have to arrange your data collection methods so that identifiers and subject responses are never linked.

Q: What is considered sensitive information?

- 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 use Survey Monkey? Mturk? Qualtrics?

- Yes, these are the accepted methods at Penn for collecting data through online platform.

Q: Can researchers audio record interviews?

- 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 must upload the company’s privacy/confidentiality policy.

Q: What does the IRB need?

- Copy of the survey or text of the questions to be asked
- Are kids involved?
- How are you getting consent – copy of consent form/script

Q: Is convened review ever required?

- Only when the data was collected without IRB approval. In these cases, the convened board will consider permission to use data.

Q: Does consent need to be documented?

- Depends on whether you want to preserve anonymity of the subjects. You may still document consent but will need to make sure documenting consent will not put your subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.
Q: What is expedited category 6?

- Collection of data from voice, video, digital, or image recordings made for research purposes.
  - In general, it is not a stand-alone category. It is usually coupled with other expedited categories such as 4 or 7.

Q: What is expedited category 7?

- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- Refers to studies that do not qualify for exempt category 2.

Q: Do I need to get documented consent?

- Documented consent is rarely required for survey studies. Researchers may seek a waiver of documentation of consent and include a verbal consent script or indicate that the completion of a survey serves as the documentation that the subject consented.

Q: What is needed for focus groups?

- Researchers need to submit a focus group script or guide which usually includes consent statement. The consent statement should include a statement that the privacy cannot be guaranteed because any of the participants may voluntarily disclose information outside of the focus group setting even if you ask them not to do so.

Q: Do I have to upload all my questionnaires/instruments?

- No, validated measures do not need to be uploaded. They need to be described and referenced only. Other questionnaires need to be uploaded.
- Researchers need to include interview guides or (for semi-structured interviews) a summary of the topics that will be discussed.
Q: Can I store data on my laptop? Jump Drive?

- Researchers should discuss data protection strategies with their LSP to make sure they adhere to department policies.
- If the data collected includes PHI, please refer to the policy on storing electronic protected health information.
- If identifiable data is stored on a laptop or flash drive it should be encrypted. This plan should be discussed in the IRB application.

Q: Can I videotape the interviews?

- Yes; however, researchers must seek permission to do so prior to videotaping and must have plans to protect the recordings obtained and destroy it once the study is complete.

Q: How do I complete the PHI section if I’m not collecting PHI?

- Researchers should still list the identifiers that you will be collecting and inform us how you will protect the data collected and whether they will be destroyed upon study completion.

Q: What does the IRB need?

- Copy of the survey/interview guide/focus group guide
- How are you getting consent – copy of consent form/script

Q: Should I use the consent form template?

- Use it only as a guide. It’s formatted for a more complicated intervention study and not a survey study. Researchers may either create your own consent form or tailor the consent form template to your study. However, they must contain the basic elements of consent. Consent forms for survey studies should be only 1 or 2 pages.

Q: What do researchers have to do if I want to use deception?

- Fill out the Deception section in the HS-ERA application. Depending on the type of deception to be used, the application may or may not need a convened IRB review. Intentionally withholding information about the research is a type of deception.
- Deception is referred to the convened IRB to assess whether the criteria for waiving informed consent has been met. In some cases (indirect deception), expedited review may be appropriate if only a minor part of the procedures is left out of the consent process
Research with existing data/specimens (Exempt category 4, Expedited category 5)

Q: What exactly is exempt category 4?

- Research involving the collection or study of existing data, documents, records, pathologic or diagnostic specimens, if these specimens are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Q: Can researchers use identifiable information and still be eligible for exempt review?

- Probably not. In order to qualify for exemption you have to be able to search the data without using identifiers and all research records must be free of identifiers.

Q: What is a limited dataset?

- A set of data that includes individual protected health information and has had all direct identifiers removed.
- It may contain elements of dates (date of birth, date of procedure) and city/state/zip code information.
- It can be shared with outside entities under a data use agreement.
- Use of limited datasets requires Exempt Category 4 per Penn policies.

Q: What does the IRB need to know when reviewing these studies?

- Where is the information coming from?
- Are you working with the Office of Research Services to obtain a data use agreement?
- Where will the data be stored once you receive it?
- Are you sharing the data with anyone else?

Q: What is expedited category 5?

- Research involving materials (data, documents, records, or specimens) that have been collected or will be collected for purposes other than this proposed research.
- Refers to studies that do not qualify for exempt category 4. Common examples are:
  - Retrospective medical record reviews
  - Secondary use of data collected by another research study
  - Prospective observation study
  - Analysis of previously collected blood and tissue specimens
Q: How does the IRB define retrospective?

- A study is considered retrospective if all the materials that will be studied have existed as of the day of IRB approval. Everything must be on the shelf at the time you start the study.

Q: What is an observational research study?

- A study is considered observational if all the procedures and subject interactions are being performed for non-research purposes. The only study activity is the collection and analysis of that data for research purposes.

Q: When do I not have to obtain consent and HIPAA authorization?

- When you meet the following criteria for a consent waiver:
  - Study poses no greater than minimal risk
  - Waiving consent does not impact subjects rights or welfare
  - You have a mechanism for returning pertinent information to subjects
  - The study cannot be practicably conducted without the waiver

- If you are requesting a HIPAA waiver for PHI you must also meet these criteria:
  - There is an adequate plan to protect PHI for improper use and disclosure
  - There is an adequate plan to destroy PHI at the earliest opportunity
  - There is an assurance that PHI will not be reused or disclosed without IRB permission
  - You are using the minimum necessary PHI to conduct the research.

Q: Can I disclose information collected under a HIPAA waiver?

- If data is fully de-identified, you can disclose the data.
- If the data is converted into a limited dataset, you can disclose the data if you obtain a data use agreement
- If the data contains direct identifiers, you can disclose the data if the IRB grants permission – this will likely require convened IRB review

Q: Can I store PHI on my laptop or flash drive?

- You should discuss data protection strategies with your LSP to make sure you adhere to department policies.
- Identifiable data should be stored on health systems computers and servers.
- If identifiable data is stored on a laptop or flash drive it should be encrypted. This plan should be discussed in your IRB application.

Note: All references to the IRB website are for the following web address: www.upenn.edu/IRB
Q: What does the IRB need to know when reviewing these studies?

- Where are the materials coming from?
- Are the materials retrospective or prospective?
- How many subject records/specimens are involved?
- Where will the data be stored once you obtain it?
- How long will you retain identifiable information? Will there be a separate linking set?
- Who will you share materials with?
- Are you obtaining consent or requesting a waiver? Why do you meet the waiver criteria?
Q: Who can serve as a Principal Investigator?

- Per Penn policies, only faculty members can serve as the principal investigator on a study.
- Exceptions to this request are rarely granted. Exception requests are considered by the IRB director.
- Students or trainees (e.g. residents) cannot serve as PI on their graduate thesis projects.

Q: Who can edit the application and submit modifications/continuing reviews for protocols?

- Individuals listed as the Principal Investigator, Study Contact, or Other Investigator.
- Individuals listed as Key Study Personnel do NOT have edit access.

Q: What is an Investigator Initiated Trial?

- A study that involves the administration of a drug, device, or biologic where the investigator holds the sponsor’s responsibility for the design and oversight of the protocol
- Typically these studies are not eligible for expedited review.
- If your study does not involve drugs, devices, or biologics, you should answer “no” to the Investigator Initiated Trial question.

Q: How do I answer the medical information disclosure study question?

- If your study involves the use or the disclosure of protected health information you should answer Yes to this question.
- Then select how you are addressing the HIPAA requirements (separate HIPAA, combined consent and HIPAA, waiver request)

Q: When do researchers need to upload a grant application?

- The grant application is needed when the study is supported by federal funds (NIH, DoD, DoE, etc.)
- Do not include the budget and appendices

Q: What if I do not want to have a target enrollment?

- Indicate an open ended enrollment in the target population or accrual section.
- Enrollment numbers should describe the approximate number of subjects that will be enrolled each year.

Q: What does the IRB need to know if researchers are storing samples for future research?

- Who controls the samples?
- Who has access to the samples?
- Will identifiers be retained?

Note: All references to the IRB website are for the following web address: www.upenn.edu/IRB
Will samples be shared outside of Penn?

Are there any other rules about who can analyze the samples or how they can be used?

Q: Do researchers have to have separate parental permission and assent forms?

- No. You can design the form to include any combination of adult subjects, child subjects, and parents.
- Make sure the forms are clear and the signature areas are well defined.
- Younger children may need an age appropriate assent form. This does not have to follow the IRB templates.

Q: What’s the difference between subjects enrolled by Penn researcher and subjects enrolled by collaborating researcher?

- Subjects enrolled by Penn researchers are subjects that you and your team will enroll regardless of where that takes place. If you go to Drexel and enroll subjects there, they still count as subjects enrolled by Penn researcher.
- Subjects enrolled by collaborating researchers are subjects that will be enrolled by people who are not part of your team. If Drexel is a collaborating site and they enroll subjects, then they count as subjects enrolled by collaborating researchers.

Q: Can researchers use social media?

Yes; however, application must clearly indicate how researchers are using social media.

- Refer to Penn IRB’s social media guidance.
- Are researchers only posting recruitment materials, are you conducting an intervention with social media, are you communicating with subjects through social media platforms.
- If employing intervention, researchers must inform the subjects about confidentiality issues and address how they will protect research data collected.
- Researchers may also need to develop a plan for monitoring social media communications between subjects.

Q: What are some considerations of international study?

- Depending on the country where you will be conducting a study and your target population and whether researchers are collaborating with a local investigator, researchers may or may not need to obtain local IRB or its equivalent approval. The investigator must consider local laws and customs when conducting research outside of the US.

Q: What are some considerations for translated materials?

- A translated consent form should be submitted with either a certificate of translation or if translated by a study staff, the background information of the person who did the translation to provide documentation that that person is qualified to do the translation. A back translation is not required.