SPOTLIGHT ON CLINICAL RESEARCH

The Role of the IRB and How to Submit Studies for Review

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Editor's note: This is the 23rd in a series of articles from the Penn Medicine Lancaster General Health Research Institute that describes ongoing research studies. Members of the LG Health staff who are conducting research and wish to have their studies described here are encouraged to contact the JLGH editorial offices.

Submitting a research study to an Institutional Review Board (IRB) can be a daunting process whether you are a first-time researcher or a seasoned investigator. For many, determining what to do, when to do it, and who to reach out to with questions can cause frustrating delays in getting a research study started. This spotlight is meant to demystify the role of the IRB and outline how to submit studies for IRB review.

The Lancaster General Hospital (LGH) IRB officially merged with the University of Pennsylvania's IRB on July 1, 2024. This merger provides expanded access to Penn's resources and expertise, but LGH researchers may now need to navigate a larger, centralized system. References to the IRB in this spotlight refer to the University of Pennsylvania (Penn) IRB.

What is the IRB?

An Institutional Review Board is a group that has been formally designated to review and monitor research involving human subjects. It is tasked with reviewing, monitoring, and approving research studies. At its core, the IRB ensures that the rights, safety, and welfare of research participants are protected. The IRB has authority to:

- Approve a study.
- Require modifications to secure approval.
- Disapprove research that does not meet ethical or regulatory standards.

The IRB may also determine whether a proposal constitutes human subjects research.

The IRB has multiple boards that review research studies across the University of Pennsylvania and the University of Pennsylvania Health System. Studies are assigned to boards based on specialty, disease state, or availability of reviewers.

Must I always submit my project to the IRB?

Any research study involving human subjects requires review by the IRB. The study must receive IRB approval before it can begin.

The Penn IRB follows the Department of Health & Human Services (HHS) Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA) definitions of *research* and *human subjects* to determine whether a project constitutes human subjects research. According to the HHS, *research* is defined as "a systematic investigation, including research development, and testing and evaluation, designed to develop or contribute to generalizable knowledge." A *human subject* is "a living individual about whom an investigator conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; OR
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Please note, researchers cannot make their own determination regarding whether research with existing private data or specimens is human subjects research. If you are unsure whether your study constitutes human research, you can:

1. *Contact the IRB* via telephone (215-573-2540) or email (PROVOST-IRB@pobox.upenn.edu). They also host office hours that anyone can join. To find upcoming IRB office hours, visit zcal.co/pennirb/officehrs.
2. *Submit a "Human Subjects Research Determination" form.* This form can be found on the Penn IRB website and can be submitted via email or via the Penn IRB system.

If the project may be quality or performance improvement, you can review the Quality/Performance Improvement (QI/PI) Guidance on the IRB website.

Visit Penn IRB online at **irb.upenn.edu**

How do I know what level of review to select in the IRB application?

Research studies require review by a convened meeting of the IRB unless the research falls into an Exempt or Expedited review category (see Table 1). Final review category and submission requirements will be determined by the IRB.

Table 1. IRB Review Categories

Exempt	Research involves *no more than minimal risk* to participants. Research procedures must fit within at least one exemption category. The Penn IRB system has eight exempt categories to choose from.
Expedited	Research involves *no more than minimal risk* and doesn't meet criteria for exempt status. The Penn IRB system has seven expedited categories to choose from.
Full Board Review	Research does *not meet exempt or expedited status;* it must be reviewed at a monthly meeting of the full IRB.

NOTE: If you select Exempt or Expedited for a study that actually requires full board review, the IRB reviewer will send the submission back to you with additional questions to answer within the application. If you are unsure which option to select, you should select "full board review." Your study will be routed by an IRB analyst for the appropriate level of review.

What should I include in the IRB application?

The application will walk you through what information is required by the IRB for the study being submitted. However, it's important to have all study documents finalized before submitting to the IRB. Study documents most commonly include:

- *Protocol:* A detailed plan of the study that includes the objective, methodology, data collection processes, analysis plans, etc.
- *Informed consent form:* A document outlining the details of the research study including the purpose, procedures, risks, benefits, and alternatives to participation (if informed consent is being obtained).
- *Investigators' brochure or drug inserts* (if the study involves a drug): Documents detailing the drug's characteristics.
- *Recruitment materials:* Flyers, brochures, posters, and other documents used for participant recruitment.
- *Data collection tool(s):* Blank versions of case report forms, questionnaires, or surveys.
- *Regulatory documents:* Approval letters, such as Investigation New Drug (IND), Investigational Device Exemption (IDE), FDA correspondence, or letters of support from departments participating in the study.

NOTE: All participant-facing materials (documents that study participants will see) must be submitted to the IRB for review and approval.

The Penn IRB strongly recommends including a cover letter with all submissions (initial or subsequent). The cover letter should provide additional information that may help the reviewer complete their review of the study and explain anything not covered in the application. It should also provide a documents list that outlines all the documents submitted with the application.

How long will it take for the study to be reviewed by the IRB?

The turnaround time depends on the type of study and type of submission being reviewed. See Table 2 for goals Penn IRB staff members set for turnaround times for review categories.

Table 2. Goals for IRB Staff Processing

Submission Type	Reviewed Within	Letter Posted
For studies that are Exempt or Expedited		
Initial Review	10 business days	Within 2 business days of Director or IRB Chair approval
Response	2 business days	
Modifications	3 business days	
For studies that require Convened (Full Board) Review		
Initial and Modification Reviews	Within ~30 days from time of submission	Within 3 business days of the meeting date
Continuing Reviews	On the day of or prior to expiration	On the day of expiration (if expiring the day of the meeting) or within 3 business days of the meeting date

What happens after submission?

A determination letter for the submission will be provided once it is reviewed by the IRB. You will receive an email when the determination letter is available. If the determination letter indicates that the study is approved, study activities may begin. If you are an LG Health researcher and would like support submitting to/interacting with the Penn IRB office or other regulatory requirements for research, please contact Heather Madara at the email address below.

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