pennsylvania
DEPARTMENT OF HEALTH

IRB FAQs

Do I Need to Submit an Application to the Pennsylvania Department of Health IRB?

If your research falls into any of the following categories, you should submit an application to the Pennsylvania Department of Health IRB:

- Research involving grants for which Department of Health programs are applying.
- Research involving grants awarded by the Department of Health to grantees.
- Research conducted by the Department of Health.
- Research involving the use of Department of Health biological specimens, protected health information, and/or data.
- Research is going to be conducted at a the Department of Health licensed/approved nursing home or long term care facility

My research falls into one of the above categories. What do I need to submit to the Pennsylvania Department of Health IRB, and how should I submit the documents?

A link to a PDF of the initial review application can be found below. Please follow the instructions below and submit the application and any other requested documents via email to RA-HealthResearch@pa.gov or mail to *Department of Health, Health Research Office, Health and Welfare Building, Room 833, 625 Forster Street, Harrisburg, PA, 17120.*

A list of categories of research that are exempt from review can be found in the application document. If you believe your project qualifies as exempt from review please take the following steps:

- Fill out the application completely from the beginning of the document through the request for exemption
- Fill out the Project Detail and Signature sections
- Submit a research protocol and relevant research training certificates

If you believe your research qualifies for expedited or full review, please take the following steps:

- Complete an Application to the Pennsylvania Department of Health's Institutional Review Board for Approval of Research Project.
    - If there are any open ended questions that are not relevant to your study, please answer N/A
- Provide all required documentation to the DOH IRB administrator. Documentation includes, but is not limited to:

  - Completed Application to the Pennsylvania Department of Health's Institutional Review Board for Approval of Research Project under the Federal Policy for the Protection of Human Subjects
  - Full research protocol
  - Proposed informed consent documents
  - Relevant grant applications
  - Relevant data request applications
  - Investigator's brochure (if available)
  - Subject recruitment materials.
- In certain types of research, HHS regulations require specific findings on the part of the full IRB, such as in the case of approving:
  - A waiver of obtaining informed consent;
  - Research involving pregnant people, human fetuses or neonates;
  - Research involving prisoners; and
  - Research involving children.

Forms

- Application
- Continuing Review
- Change of Protocol
- Adeverse Event Reporting

How does the IRB review my research application?

If you apply for the IRB and submit a reason for exemption, a primary review team composed of the chief of the IRB and two other members will review your application for exemption. Upon reviewing the application, the primary review team will notify the researcher whether the research was approved as exempt or a full application needs to be submitted.

If you apply for the IRB and request expedited review, a primary review team composed of the chief of the IRB and two other members will review your application. After reviewing the entire application, the primary review team will then make one of three decisions. They may notify the researcher that the project has been approved. They may request minor protocol modifications by the researcher prior to approving. They may determine that the application must undergo full review by the entire IRB rather than expedited review.

If your application is undergoing full review, all members of the IRB (consisting of at least five members) will review the application. The IRB may make one of several decisions regarding the application. The IRB may approve the research. The IRB may disapprove of the research. The IRB may request certain modifications to the proposal prior to approval. The IRB may state that approval will be given if the research project complies with certain conditions determined by the IRB.

How often does my project need to be reviewed following initial approval?

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Projects must be reviewed at least once per year following initial approval. At the discretion of the IRB, projects may need to undergo more frequent continuing reviews.

If my project requires a continuing review, what should I do?

Please submit the continuing review document linked below via e-mail to ra-healthresearch@pa.gov. Fill out the document in its entirety and submit any required attachments as stipulated in the document.

I need to change my already approved protocol. What should I do?

Please submit the protocol change request form linked below via e-mail to ra-healthresearch@pa.gov. Fill out the document in its entirety and submit any required attachments as stipulated in the document.

What should I do if there are any risks to the subject that were not anticipated in the initial review?

The IRB needs to be notified of any unanticipated risks to the subjects. Please write a description of the risks in a word document and submit the document to the DOH IRB administrator via e-mail to ra-healthresearch@pa.gov.

What should I do if I find that part of my experiment is out of compliance?

The IRB needs to be notified of any noncompliance. Please write a description of the noncompliance in a word document and submit the document to the DOH IRB administrator via e-mail to ra-healthresearch@pa.gov.

I have a question that is not listed here. Who should I contact to answer my question?

Please email your question to the DOH IRB administrator using the email ra-healthresearch@pa.gov.