PRESBYTERIAN

Human Research Protections and
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INSTRUCTIONS FOR SUBMITTING APPLICATIONS FOR NEW STUDIES

Presbyterian Healthcare Services (PHS) has established an Institutional Review Board (IRB) to ensure the protection of human subjects in research conducted under the auspices of the PHS. All non-exempt human subject research conducted under the auspices of PHS must be reviewed and approved by the PHS IRB or another designated IRB prior to the initiation of the research unless it has been determined that PHS is not engaged in the research. The PHS IRB derives its authority from federal regulatory sources (45 CFR 46.107) and from PHS policy (IRB.PHS-E.002).

Research is "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge" 45 CFR 46.102(d).

Research is considered to involve **human subjects** when an investigator conducting research obtains:

(1) Data through intervention or interaction with a living individual, or
(2) Identifiable private information about a living individual (45 CFR 46.102 (f)).

Human subjects research may include surveys and interviews, behavioral investigations, retrospective reviews of medical information, experiments with blood and tissue, and demonstration and service programs and clinical trials. In addition, the FDA includes under the definition of reviewable research, any use of a FDA regulated product except for use of a marketed product in the practice of medicine.

If you believe your study meets the criteria for **"exempt"** status, you must complete a **"Request for Determination of Exempt Status"** form (available on IRBNet). The determination of exempt status must be made by a disinterested person knowledgeable in the interpretation of human subjects research regulation and guidance. At PHS, this responsibility is delegated by policy to the Human Research Protections Office (HRPO) staff and/or the IRB Chair, who also have the authority to require modifications to exempt research in order to ensure protections of human subjects. If a study qualifies as exempt, then it is exempt from expedited or full board IRB review.

If your research activities do not fall under one or more of the specified exempt categories, you will need to submit the **"Application for a New Study: Non-Exempt (Expedited and Full Board Review)"** for IRB review. Investigators are not permitted to make changes to the research without IRB review. Before any changes can be implemented, you must notify the IRB by submitting an amendment request.

INSTRUCTIONS FOR SUBMISSION

1. **Protection of Human Research Subjects Training Course (CITI)**

   PHS requires investigators, coordinators, and key personnel involved in the research to complete CITI training in the ethical use of human participants in research. Re-training is required every three years. CITI training instructions are available on IRBNet, and additional information is available at https://www.citiprogram.org/. If you have any further questions, contact the HRPO at 505-841-1436 or PHSresearch@phs.org. The application will not be processed until all study personnel have completed CITI training.

   Required CITI Modules: If you are conducting social/behavioral research, choose **"Social-Behavioral Research Investigators"** under Question 1 when selecting your curriculum on the CITI webpage. If you are conducting biomedical research, choose **"Biomedical Research Investigators"** under Question 1 when selecting your curriculum on the CITI webpage.

2. **Investigators**

Principal Investigator: Conducting research with humans is a privilege and carries with it ethical and legal responsibilities. The Principal Investigator (PI) is the individual responsible for writing an accurate protocol to utilize human subjects. Ultimately, the PI assumes the responsibility for the ethical conduct of the project and for the welfare of the human subjects. This responsibility includes the intellectual conduct of the project, fiscal accountability, administrative aspects, and the project's adherence to relevant policies and regulations.

Affiliated Investigator: any individual who is qualified by experience, education, and training to conduct research at PHS, and who falls into one of the following categories:

- A physician or advanced-practice clinician with clinical privileges at a PHS facility;
- A private-practice physician on the PHS medical staff who does not have clinical privileges;
- A paid employee of PHS, including an employee currently enrolled as a student in an academic program related to the study;
- An employee of a PHS-contracted service (e.g., Tricore Labs, Radiology Associates of Albuquerque); or
- A resident who is participating in a program which has a clinical affiliation agreement with PHS.
- Affiliated investigators may act as the Principal Investigator (PI).

Unaffiliated Investigators: any individual who

- Does not meet the above affiliation criteria (for example, a resident participating in a program which does not have a clinical affiliation agreement program with PHS or a private-practice physician without clinical privileges); and
- Proposes to conduct research using any PHS property, facility, patient/employee population, or non-public information.

Student Investigators: Student investigators must be paid PHS employees in order to initiate a research project at PHS. Student investigators must also identify a study mentor who will provide guidance and oversight of the proposal development/submission process and the conduct of the research. Study mentors must formally approve and sign off on student applications.

3. **Submission Process**

New PIs (along with at least one other member of the study team) are required to register with IRBNet at https://www.irbnet.org/release/index.html. Please submit completed application and ALL relevant materials via IRBNet. All supporting materials must be included with the application for review and approval by the IRB (see checklist below). All required materials need to be submitted by the 10th day of the month to be considered for inclusion on the next IRB agenda. The workload of the Human Research Protections Office (HRPO) necessitates that submissions received after midnight on the 10th will be assigned to the next month's agenda. The IRB meets on a regular basis throughout the year (typically on the fourth Tuesday of the month). The schedule for the IRB may vary due to holidays or lack of quorum. The schedule for IRB meetings is posted on IRBNet.

A designated HRPO staff or IRB representative is responsible for reviewing the application. The HRPO will notify the PI if the IRB needs additional information or clarification about the research project. The IRB also has the authority to request that a protocol undergo a different review level than submitted. When the IRB has approved the application and CITI training is completed by all applicable personnel, the HRPO will send a determination letter via IRBNet to the PI.

STUDY ACTIVITIES MAY NOT BEGIN UNTIL NOTIFICATION OF APPROVAL FROM THE IRB HAS BEEN RECEIVED.

INVESTIGATOR SUBMISSION CHECKLIST (AS APPLICABLE)

*For investigator use only; these pages **do not** need to be submitted with the protocol application.*

☐ Completed "Application for a New Study: Non-Exempt (Expedited and Full Board Review)" form; or
☐ Completed "Request for Determination of Exempt Status" form;
☐ A cover letter summarizing the study, including study objectives, methodology, and personnel;
☐ Detailed research protocol (please use the "Protocol Template with Guidance" form on IRBNet);
☐ Sponsor protocol/investigator brochure;
☐ HIPAA authorization or request for waiver of HIPAA;
☐ Informed consent documents (consent form, assent form, parent permission form, cover letter, verbal consent script, etc.) or request for waiver of consent;
☐ Recruitment materials (advertisements, posters, flyers, scripts, etc.) intended to be seen or heard by participants;
☐ Data collection instruments (questionnaire/survey, interview questions, scripts, etc.);
☐ Permission/acknowledgement letter from external site;
☐ Departmental/organizational unit approval forms;
☐ Financial conflict of interest form;
☐ CITI (human research protections training) completion certificates for all investigators and study staff;
☐ Signed and dated CVs/resumes for investigators and study staff;
☐ Copies of professional licenses for investigators;
☐ Publications related to the study;
☐ Grant proposal (if receiving or requesting external funding).