Guidance - Use of Human Subjects in Pilot Studies, Oral Histories and QA/QI Projects

There are some types of studies that trigger questions and require further discussion with respect to investigators' responsibilities and the need to obtain prospective review and approval of the IRB:

- Student/Trainee Projects
- Pilot Studies
- Oral Histories
- Quality Assurance/Quality Improvement Projects

Human Subject Research

There are some additional activities where is it difficult to determine whether the activity meets the criteria of human subject research where submission and review by the IRB is necessary. Those activities could include case reports, program evaluation, and surveillance activities. Please contact HRPP staff for questions or additional information.

IRB members and researchers can check the HRPP website linksIs my activity research? "Guides to Initiate Your Research" for additional guidance.

Student/Trainee Projects

Geisinger supports student and training projects involving human subjects. Directed or independent projects by residents, nurses, graduate or undergraduate which involve human subjects must be submitted and reviewed by the Geisinger IRB. These projects could include independent undergraduate research projects, masters' theses and dissertations, etc.

Pilot Studies

A pilot study is a preliminary investigation of the feasibility of a study, usually done on a small scale (approximately 10 or fewer subjects) and exploratory in nature. It is designed to help the investigator refine data collection procedures and instruments or prepare a better, more precise research design. Such a pilot would not contribute to generalizable knowledge and therefore questions can be raised whether or not pilot studies would be considered human subject research and require IRB review. **If a pilot study is not considered human subject research, data collected from a pilot study cannot be used as research data.**

Medical interventions or interactions for research purposes, especially those involving invasive procedures, require IRB review regardless of the size of the study.

Oral History

An oral history study may not require IRB review because it is not generally thought to be a systematic investigation designed to contribute to generalizable knowledge beyond the individual being interviewed. However, when using oral history as a technique in human subject research it may require IRB review. Researchers proposing such work are strongly encouraged to contact the IRB to determine whether their project requires approval.

Quality Assurance/Quality Improvement Projects/Program/Surveillance Activities

Research conducted in conjunction with program evaluations or quality assurance measures may or may not fall under the jurisdiction of the IRB. If such a project is conducted with the intent to develop or contribute to generalizable knowledge, it should be submitted for IRB review. For clarification, researchers are encouraged to contact the IRB staff to discuss the details of the project..

- Electronic application submission via iRIS.
- Visit the HRPP website
- For an IRB determination of whether the study requires IRB review, researchers must complete and submit the Research Determination Worksheet to bkent@geisinger.edu