

Guidance on Activities Not Under the Jurisdiction of the Institutional Review Board

The University of Pittsburgh IRB is required by federal regulation to review projects that meet the definition of human subject research. There are other types of activities undertaken by faculty, staff, and students that may not require IRB approval. Examples of those activities are as follows:

Case Reports

A summary of clinical data, including medical history and other relevant information, that was collected initially for the purposes of analyzing and diagnosing the individual's condition and/or for instructional purposes, is considered by the IRB to be a 'case report' or 'case study'. Because this information was not collected with any intent to test hypotheses or otherwise produce 'generalizable' knowledge, the activity does not meet the criteria for 'research' (45 CFR 46.102(d)), and ordinarily does not require IRB oversight. If more than one case occurs of the specific condition or medical anomaly, and the publication gathers those cases in an effort to generalize the outcomes or the investigators begin to formulate a hypothesis or attempt to gather further information on cases of this type with the intent to publish the results, activities cross into what would be considered "Research" and investigators must submit a research proposal to the IRB.

Although publishing a case report may not require submission to the IRB, investigators should be aware of the use of individually identifiable health information in their publications. Under HIPAA, the disclosure of an individual's protected health information must be authorized by that individual. In other words, if a case report contains any identifiers as defined by the HIPAA regulations, authorization to disclose this information in a publication must be sought from the individual whose information is being disclosed. The subject must sign an authorization to disclose this information and that authorization must be reviewed by the institutional Privacy Board (the IRB can serve in that function for UPMC facilities). When the report includes a description of a patient with a rare disorder, condition, or course of treatment, a HIPAA authorization will usually be required because those individuals may be more easily identified.

Innovative Practice

Two passages from the Belmont Report are particularly relevant to any discussion of what constitutes 'innovative practice'.

For the most part, the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. By contrast, the term "research" designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is "experimental," in the

sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project.

Innovative or newly-introduced clinical procedures or therapies do not require IRB review and approval except when they meet the definition of 'research'. An innovative clinical practice is an intervention designed solely to enhance the well-being of an individual patient or client. The purpose of an innovative clinical practice is to provide diagnosis, preventative treatment, or therapy to particular individuals. The introduction of innovative procedures or therapies into clinical practice (i.e., independent of a research activity approved by the IRB) should be reviewed with the applicable UPMC oversight committee (e.g., Pharmacy and Therapeutics Committee; Innovative Practices subcommittee of the Technology Assessment Committee) prior to their implementation.

Program Evaluations

Program evaluations involve the systematic collection and analysis of information about the effectiveness of the program in order to make judgments about the program, improve program effectiveness, and/or inform decisions about future program development. These evaluations may involve various methods of human interaction such as surveys, interviews, and the analysis of documents and background information. However, if the intent of these projects is to inform particular programs about that program's effectiveness and needs rather than to contribute to generalizable knowledge, they are not considered research. Nonetheless, there may still be ethical issues associated with program evaluations such as risks to participants and privacy and confidentiality concerns that should be considered by the investigator.

Quality Assurance and Quality Improvement (QA/QI) Projects

Quality assurance projects do not require IRB review and approval except when they involve "Research" as defined by the federal regulations). Precise definitions to permit the distinction between research studies and QA/QI projects have not been established. In general, QA/QI projects are focused primarily on improving patient care within a given patient care environment (e.g., hospital or health care organization) and, as such, the outcome of the project may not be generalizable to other patient care environments. Publication of a quality assurance project does not, per se, render that project "research"; however, if the outcome of a quality assurance project is published, attention should be given to avoiding the terminology "research" in the publication.

Please refer to the UPMC policy for projects being conducted at the UPMC <http://infont2.upmc.com/Policies/systemwide/Documents/HSPS0504.pdf>.

Research Practica/Research Methods Classes

Frequently, University Schools and Departments offer courses that require students to undertake projects in which other people are interviewed, observed, or otherwise serve as participants. The purpose of these courses is to train students and provide them with a closer view of social, educational, or psychological processes, and an opportunity to practice various research methods. Provided the data obtained will not contribute to generalizable knowledge or be published outside of the classroom and will not result in an article, master's thesis, doctoral dissertation, poster session, abstraction or result in any other publication or presentation, they are not considered human subject research that require IRB oversight. Regardless, students participating in these didactic activities should receive adequate training in how to work with participants ethically. All of these activities should also be consistent with the ethical standards and applicable rules of their profession. The IRB can provide appropriate training resources, as needed.

Research On or Involving Deceased Individuals

Research performed on individuals who have been declared legally dead and/or research involving the collection of tissues from deceased individuals is not subject to prior review and approval by the University of Pittsburgh IRB. (Note that the Federal Policy regulations governing human research subject protections defines a "Human Subject" as "a living (emphasis added) individual about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual or 2) identifiable private information.) There are, however, ethical issues associated with research conducted on or involving deceased individuals. To address these ethical issues, all University faculty who desire to perform Research on or involving deceased individuals must submit a project application for review and approval by the Committee on Research Involving the Dead. Note that, as per UPMC policies, research involving the medical records of deceased individuals is subject to obtaining the written consent of the decedents' next -of-kin or the executors of the decedents' estates. For studies that include BOTH living and deceased subjects, the IRB is the institutional committee with jurisdiction for oversight and approval. For more information on this topic, visit <http://www.clinicalresearch.pitt.edu/irs/corid/index.cfm>.