What Types of Activities Require IRB Review?

Overview

All activities, regardless of funding source or whether the activity is funded, that involve the engagement of Lehigh University faculty, staff, and students in the conduct of human subjects research must be reviewed and approved by the IRB, or determined to qualify for exempt status by the Research Integrity office. In general, the activity must meet the definition of “research” and the research must involve “human subjects” in order to fall within the purview of the IRB. Nevertheless, it is important to be aware that there are some exceptions to this rule.

Important Definitions

1. **Research** means a **systematic investigation**, including research development, testing and evaluation, **designed** to develop or contribute to **generalizable knowledge**.

   *Systematic investigation* means a study or examination involving a methodical procedure or plan.

   *Generalizable knowledge* means conclusions, facts, or principles derived from particulars (individual subjects, medical records, etc.) that are applicable to or affect a whole category (members of a class, kind, or group, a field of knowledge, etc.) and enhance scientific or academic understanding.

   *Design* refers to the purpose of the investigation. Some investigations are exploratory or are intended to train students and are not designed to produce generalizable knowledge. It is important to note that although some projects involving qualitative data collection or projects that are exploratory in nature may not have specific aims and hypotheses at the outset of the research, these are still **systematic investigations designed to contribute to generalizable knowledge** if the purpose of the project is to archive results for future research, compare results to other assessments, or draw conclusions.

2. **Human Subject** means a living individual **about whom** an investigator conducting **research** obtains:

   (1) data through **intervention** or **interaction** with the individual or (2) identifiable **private information**.

   *Intervention* includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

   *Interaction* includes communication or interpersonal contact between investigator and subject.

   *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical or school record). In order to meet the above definition, private information must be individually identifiable (i.e., the identity of the subject is known or may readily be ascertained by the investigator or associated with the information) in order for the investigation to constitute research involving human subjects. In general, private information is considered to be individually identifiable when it can be linked to specific individuals by the investigator(s) either directly or indirectly through coding.
systems, or when characteristics of the information obtained are such that by their nature a reasonably knowledgeable person could ascertain the identities of individuals.

3. *Exceptions to the above definitions*

*Coded Private Information or Biological Specimens:* As explained above, private information is generally considered to be identifiable when it can be linked to specific individuals by the investigator either directly or indirectly through coding systems. However, under specific conditions, coded private information or biological specimens are not considered to be individually identifiable and their use would not be considered research involving human subjects. See Research with Coded Private Information or Biological Specimens below.

**Activities that Generally Require Review**

1. **Master's Theses/Doctoral Dissertations** involving human subjects.
2. **Pilot Studies** involving human subjects.
3. **Clinical Investigations** including research to increase scientific understanding about normal or abnormal physiology, disease states or development, and research to evaluate the safety, effectiveness or usefulness of a medical product, procedure, or intervention. Vaccine trials, medical device research, and cancer research are all types of clinical investigation.
4. **Behavioral and Social Sciences Studies** such as investigations on individual and group behavior, mental processes, or social constructs. These usually generate data by means of surveys, interviews, observations, studies of existing records, and/or experimental designs involving exposure to some type of stimulus or environmental intervention.
5. **Epidemiological Studies** such as investigations on health outcomes, interventions, disease states and conclusions about cost-effectiveness, efficacy, efficiency, interventions, or delivery of services to affected populations. This research may be conducted through surveillance, monitoring, and reporting programs. Other methods may include retrospective review of medical, public health and/or other records.
6. **Human Genetic Research** such as pedigree studies, positional cloning studies, gene transfer research, longitudinal studies to associate genetic conditions with health, health care, or social outcomes, and gene frequency studies.

**Activities that May Not Require Review**

1. **Class-Related Research Activities** involving research methodology and course-assigned data collection. These activities generally do not constitute research because their purpose is to provide training in research as part of the overall educational mission of a program and are not designed to contribute to new knowledge. However, if, for example, a student is involved in an activity designed to teach research methodologies and the instructor or student wishes to conduct further investigation and analyses in order to contribute to scholarly knowledge, the design of the project has changed such that it meets the above definition of research and requires IRB review. Regardless of when this change occurs, the IRB must at this time review the research. *Course instructors are responsible for assessing whether these activities meet the definition of research as delineated above and are encouraged to contact the Research Integrity office for assistance if needed.*

2. **Quality Assurance/Quality Improvement Activities** that attempt to measure the effectiveness of programs or services, including program evaluations, model curriculums, or needs assessments. Such activities are not typically designed to be generalizable to the larger community and would not be considered research if results will not be compared with other assessments. *Those responsible for such projects must be certain that their activities are not human research.*

3. **Repository Research, Tissue Banking, and Databases** utilizing stored data or materials (cells, tissues, fluids, and body parts). If the investigator cannot readily ascertain the identity of the subject from whom the data or materials originated (i.e. the data is stripped of identifying information, or coded and the investigator does not have access to the key), these activities would not require IRB review. *However, repository research, tissue banking, and databases utilizing stored data or materials (cells, tissues, fluids, and body parts) from individually identifiable living persons must be reviewed by the IRB.*
4. **Case Reports** utilizing private identifiable information such as medical information collected from a clinical activity. Case reports are generally carried out by retrospective review of records and highlight a unique treatment, case, or outcome. As the collection and organization of information for such reports usually involves no data analysis or testing of a hypothesis, they do not involve systematic investigation. Therefore, single case reports are not research and would not require IRB review. However, retrospective record reviews that incorporate data collection and data analysis to answer a research question must undergo IRB review. Additionally, meta-analysis of multiple case reports to examine and compare interventions or cases is considered to be human subjects research.

5. **Research on Institutions or Social Processes** when the intent or focus of the research is to gain knowledge of an institution or social process (e.g., a political party, labor negotiations) and this research is not intended to produce generalizable knowledge about any particular individual or groups of individuals. Often, investigators wish to collect information from individuals about institutions or social processes. Such an activity is not human subjects research when the focus of the research is not on characteristics of an individual or groups of individuals because the information collected from the informant is not about the informant. There is often a fine line between human subjects research and research that collects information from individuals in order to understand institutions or social processes. Research on institutions or social processes, the purpose of which is to create generalizable knowledge about the attitudes, beliefs, or behaviors of individuals or groups (e.g., voters, prisoners, employees, teachers) as being representative of these institutions or social processes, is human subjects research.

**Qualitative Interviews and Human Subject Research**
The decision concerning whether activities that consist of open-ended qualitative type interviews (such as oral history projects or ethnographies) require IRB review hinges upon whether the activity meets the above definition of research—specifically, whether the activity is “designed to contribute to generalizable knowledge.” The purpose of these activities is often to create a record of specific historical events and, as such, is not to generalize findings to a broader population or group. However, activities involving similar characteristics may be “designed to contribute to generalizable knowledge.” Below are examples of qualitative interviews that are considered to be research and examples of qualitative interviews that are not considered to be research.

Examples:
- An oral history video recording of interviews with Holocaust survivors is created for viewing in the Holocaust Museum. The creation of the videotape is not intended to prove a hypothesis, inform policy, or draw conclusions. The sole purpose is to create a historical record of specific personal events and experiences related to the Holocaust and provide a venue for Holocaust survivors to tell their stories. Open-ended interviews that only document a specific historical event or the experiences of individuals without the intent to draw conclusions or generalize findings would not constitute research.
- Open-ended interviews are conducted with surviving Gulf War veterans to document their experiences in order to draw conclusions about those experiences, inform policy, and generalize findings. This would constitute research.
- Open-ended interviews are conducted with surviving Negro Baseball League players in order to create an archive for others to analyze and generalize findings in the future. Since the intent of the archive is to create a repository of information for others to use in research, the creation of such an archive would constitute research.

**Research with Coded Private Information or Biological Specimens**

*Coded Private Information or Biological Specimens* means that identifying information (such as name, social security number, medical record number) is replaced with a code comprised of numbers, letters, or a combination thereof; and a key to decipher the code exists, enabling linkage of the individual’s identity to specimens or data.
Research involving coded private information or biological specimens, under specific conditions, is not considered to involve “human subjects” (OHRP Guidance on Research Using Coded Private Information or Specimens (2008)). Coded private information or specimens are not considered to be individually identifiable and therefore would not fall within the definition of research involving human subjects, if the following conditions are both met:

1. the private information or specimens were not collected specifically for the currently proposed project through an interaction or intervention with living individuals; and
2. the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain as a result of one of the following circumstances:
   a. the investigators and the holder of the key have entered into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (NB: DHHS regulations for human subjects research do not require the IRB to review and approve this agreement);
   b. there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigator under any circumstances, until the individuals are deceased; or
   c. there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

Examples of research with coded private information that does not involve human subjects:

- An investigator receives only coded information on the treatment outcomes of patients treated for arthritis with Drug A versus Drug B from the patients’ treating physician. The only involvement of the treating physician is to provide coded information to the investigator. The investigator and the treating physician enter into an agreement prohibiting the release of the key to decipher the code to the investigator under any circumstances, until the individuals are deceased. In this example, the investigator is not conducting human subject research because the data was not collected specifically for the proposed project, but rather during the course of the patients’ treatment, and the investigator cannot readily ascertain the identity of the individuals.

- As part of her dissertation research Student G plans to examine the relationships between ADHD, oppositional defiance disorder, and teen drug abuse using data collected by agencies H, I, and J that work with “at risk” youth. The data will be coded and the key to identifiers will be destroyed before the data is given to the student. In this example, the student is not conducting research involving human subjects because the data was not collected for the purpose of her research, it was collected for the purposes of the individual agencies, and she cannot readily ascertain the identity of the individuals.

Examples of research with coded private information and biological specimens that does involve human subjects:

- An investigator obtains individually identifiable information on the treatment outcomes of patients treated for arthritis with either Drug A or Drug B by viewing patients’ existing individually identifiable medical records at the clinics where the patients were treated. The investigator records the patients’ treatment outcomes in a coded manner but has a key to decipher the code that could permit the identification of the patients. In this example, the investigator is conducting research with human subjects because the investigator is obtaining identifiable private information from patients’ (and now subjects’) medical records.

- Professor Q has finished a project on the intertribal exchange of healers and ritual experts in East Africa; however, the information she collected could provide insights into the processes generated by the encounter between biomedicine and African traditional medicine and she wishes to use the now-coded data for another study. Professor Q has retained the key to identifiers in case she decides to do a follow-up study at a later date. Although the information was not collected specifically for the current project (i.e., the new study), the current project is still human subjects research because the professor has retained the key to identifiers.

This guidance was adapted, with permission, from U.C. Berkley Human Research Protections Program’s “What Needs CPHS/OPHS Review” website.