

What Requires IRB Review and Approval (HRPP 1.8)

Description:

This policy describes the investigational activities that require IRB approval.

Definitions:

Research:

- *Federal Policy & HIPAA Privacy Rule definition:* any **systematic investigation**, including research development, testing, and evaluation, **designed to develop or contribute to generalizable knowledge**
- *Belmont Report definition:* designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements and relationships)

Human Subject: a living individual about whom an investigator conducting research:

- 1) Obtains information or biospecimens through intervention or interaction with the individual and uses/studies/analyzes it. or
- 2) Obtains/uses/studies/analyzes/generates identifiable private information or identifiable biospecimens.

Generalizable Knowledge: information that is expected to expand the knowledge base of a scientific discipline or other scholarly field of study and yield one or both of the following:

- 1) Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied.
- 2) Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.

Note that publication or other dissemination of findings does not in and of itself make the activity “research”. It has been a long-standing myth that if you publish, IRB review is required.

Classifications of Human Subject Research:

Biomedical: the intent is to develop or contribute to generalized knowledge about human biological systems and processes and can be “therapeutic” or “non-therapeutic”.

Human Biological Material (HBM): collecting and/or using human biological specimens obtained directly from human subjects or from other sources for the purposes of research.

Medical Records: utilizes medical or clinical records with subject identifiers for both retrospective and prospective studies.

Behavioral/Social Science: the intent is to study behaviors, attitudes, and interactions and social processes.

Activities That Are NOT Human Subject Research:

The following activities are NOT considered human subject research and do not require IRB review and approval.

- Systematic investigation involving data or HBM obtained from living individuals where (a) there are **no identifiers** to readily identify the individual and (b) the specimen or data **wasn't collected specifically for purposes of research.**
- Innovative therapies that do not differ significantly from routine practice and are based upon sound clinical judgment.
- **Quality improvement (QI) activities:**
 - Take place in a particular localized setting (such as health care/clinic), their design is expected to incorporate the specific features of the setting, they are led by people who work in that setting, and they incorporate rapid feedback of results to bring about positive change for the patients in that setting.
- **Program assessments**
 - Intent is to evaluate a specific program, only to provide information for and about the program.
 - Activities are not designed to develop or contribute to generalizable knowledge.
 - Activities are mandated by the program, usually its funder, as part of its operations.
 - Findings of the evaluation are expected to directly affect the conduct of the program and identify improvements.
 - No benefit to participants is expected; evaluation concentrates on program improvements or whether the program should continue.
- **Case reports of 3 or fewer patients or activities**
- **Student projects**
 - involves living individuals but is performed solely to meet educational requirements of a single course providing the results are presented only within the confines of the classroom (or similar forum) and to the students, their instructors, parents/family members, or limited number of other invited guests.

- **Pilot testing**
 - Limited to interventions intended to test the equipment or the methodology, or to refine the parameters of the protocol, or to train the student to use the equipment.
 - Not explicitly named as one of the aims of the research.
 - Data generated from the pilot testing is not retained after the completion of the specific goals.
 - The data generated is not presented in any public format nor used as a background material for a grant application or similar purpose.
 - Will only involve healthy volunteers (preferably research staff) as participants.
 - Procedures constitute no greater than minimal risk.
 - Any data that will be used for a grant application must have IRB approval before obtaining.
- Secondary research involving **non-identifiable newborn screening blood spots**.
- **Scholarly and journalistic activities** examples: oral history, journalism, biography, literary criticism, legal research, and historical scholarship, including the collection and use of information that focuses directly on the specific individuals about whom the information is collected.
- **Public health surveillance activities:** the collection and testing of information or biospecimens conducted, supported, requested, ordered, required, or authorized by a public health authority.
- Collection and analysis of information, biospecimens, or records by or for a **criminal justice agency** for activities **authorized by law or court order** solely for **criminal justice purposes**.
- Authorized operational activities in support of **intelligence, homeland security, defense, or other national security missions**.

Does my project require IRB review?

If one is unsure if their activity needs IRB review, they can:

- 1) Use the [DECISION TOOL](#)
- 2) Contact the ORA (IRBORA@unmc.edu)