What Requires IRB Review and Approval (HRPP 1.8)

Description:

This policy describes the investigational activities that require IRB approval.

Definitions:

Research: any **systematic investigation**, including research development, testing, and evaluation, **designed to develop or contribute to generalizable knowledge** (i.e. knowledge that can apply beyond the study)

- *"Systematic Investigation"* = has clear objectives, methods, data collection, and analysis plan
- *"Generalizable Knowledge"* = meant to inform others or be repeated/applied beyond the study

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.

- **Intervention**: physical procedures (e.g. blood draws) or changes to the subject's environment
- **Interaction**: communication (e.g. interviews, surveys)
- **Private information:** behavior or data shared with expectation of privacy (e.g. medical records)
- **Identifiable**: can be linked back to a specific person

Engagement in Human Subject Research:

The organization is *engaged* in research when it's faculty, staff, or students are:

- Collecting data or biospecimens from subjects,
- Getting identifiable private information, and/or
- Obtaining informed consent

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.

1) **De-identified Data or Specimens:**
    a. If investigators cannot identify individuals, and the data/specimens were not collected for the current study, it's not human subject research
    b. **NOTE**: HIPAA rules may still apply if health information is involved
2) **Innovative Therapy:**
    a. Innovative therapies that do not differ significantly from routine practice and are based upon sound clinical judgment
3) **Quality Improvement (QI):**
    a. Take place in a localized setting, expected to incorporate specific features of the setting, are led by people who work in that setting, and incorporate rapid feedback of results to bring about positive change for the people in that setting
4) **Program Assessment (or Evaluation):** a systematic collection of information about a specific program's activities, characteristics, and outcomes used internally to improve the program or inform decisions about it
    a. ***Characteristics***:
        i. **Purpose is internal:** evaluate a specific program, not to contribute to generalizable knowledge
        ii. **Not designed as research:** no randomization or hypothesis testing, though may involve comparing different versions of a program
        iii. **Required by the program** or its funders as part of routine operations
        iv. **Results will directly impact the program's operations;** used for accountability or improvement
        v. **No benefit expected for participants;** focus is on program performance, not on individual outcomes
5) **Case Reports of less than 4 patients or activities**

6) **Student Projects:**
    a. ***When Student Projects are NOT Research:***
        i. Conducted only to **fulfill a course requirement**
        ii. Results are **only shared within the classroom** or with instructors, peers, or a limited audience (e.g. family)
        iii. **Not presented in public forums,** such as student research fairs, conferences, or journals
7) **Pilot Testing:**
    a. ***When Pilot Testing is NOT Research:***
        i. **Purpose is technical:** to test equipment methods, or train personnel
        ii. Not explicitly named as one of the aims of the research *(i.e. not part of the main research objectives)*
        iii. **Data is discarded** after pilot objectives are completed
        iv. Data is not published, presented or used in grant proposals
        v. Only involves **healthy volunteers**, preferably research staff
        vi. Procedures only involve **minimal risk**

    NOTE: If ANY of the above conditions are not met, the pilot test may qualify as research and may require IRB review and approval.

8) **Secondary Research Involving Non-Identifiable Newborn Screening Blood Spots**

Does my project require IRB review?

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

1) Use the decision tool located in RSS. Instructions for accessing the tool can be found HERE.
2) Contact the ORA (IRBORA@unmc.edu)