Code of Federal Regulations: Defining Human Subjects Research

Federal research regulations define it as: (1) a systematic investigation, including research development, testing, and evaluation, (2) designed to develop or contribute to generalizable knowledge.

What does that mean?

- (1) systematic investigation: hypothesis testing; multiple subjects, same set of questions; comparison over time versus a single story or case; no set hypothesis; phenomenologic activity (wherever the conversation goes)
- (2) generalizable knowledge: draw general conclusions about multiple cases/stories; apply knowledge broadly to a group versus describing one story/case; anecdotal information.

Must be both of these; this is only the first step.

Next Step: Human Subject

Federal research regulations define a human subject as: a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

Human Subject definition, broken down

- Intervention: both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes
- Interaction: communication or interpersonal contact between investigator and subject.
What does that mean?

- 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 (for example, a medical record).

- Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects.

Human Subjects Research

- In order for a project to require IRB review, it must be both research and involve human subjects.

Examples of projects/studies that do not need IRB review

- Searches of existing literature
- Quality assurance activities or evaluation projects designed for self-improvement or program evaluation, not meant to contribute to “generalizable” knowledge
- Interviews of individuals where questions focus on things not people or the 3 P’s policy, practice, procedures

QA/QI

<table>
<thead>
<tr>
<th>Research</th>
<th>QA/QA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose</td>
<td>To test a hypothesis OR to establish clinical practice standards where none are already accepted&lt;br&gt;To assess or improve a process, program, OR to improve performance as judged by established/accepted standards</td>
</tr>
<tr>
<td>Starting Point</td>
<td>To answer a question or test a hypothesis&lt;br&gt;To improve performance</td>
</tr>
<tr>
<td>Data Collection</td>
<td>Systematic data collection&lt;br&gt;Systematic data collection</td>
</tr>
<tr>
<td>End Point</td>
<td>Answer a research question&lt;br&gt;Improve a program/process/system</td>
</tr>
<tr>
<td>Testing/Analysis</td>
<td>Statistically prove or disprove hypothesis&lt;br&gt;Compare a program/process/system to an established set of standards</td>
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Determination Form

- Use the determination form to determine if you need IRB review
- If you know you need review, do not start with the determination form, you can still ask us which form is appropriate for submission
- Researchers can still decide for themselves without submitting a determination form
- Determination form is also used if you want/need documentation of our decision

Training

- All researchers and staff listed on new exempt, biomedical and social IRB applications are required to document completion of Collaborative Institutional Training Initiative basic human subject’s protection training and provide the date the training was completed. Researchers and staff listed on new IRB applications must have successfully completed either the basic or refresher course within the last three years.
Training

Researchers and staff listed on Health and Biological/Medical applications are required to complete the CITI Group 1 Biomedical Research Investigators and Key Personnel training course or the Biomedical Refresher if the initial course was completed more than three years from the application date.

Training

Researchers and staff listed on Social and Behavioral Sciences applications are required to complete the CITI Group 2 Behavioral or Humanist Research Investigators and Key Personnel training course or the Social-Behavioral-Educational Refresher if the initial course was completed more than three years from the application date.