“The Categories”

When It’s Not So Obvious

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“The Categories” – When It’s Not So Obvious

To those who make important decisions based on specific research standards, the categorization of projects as research is serious business and a series of (?) must be asked.
Types of Review

- Full Board
- Expedited
- Exempt
HHS requested comment regarding proposed changes to the Common Rule.

Revising exempt research to:
- Increase protections
- Broaden the types of studies covered

These studies would be described as “Excused” from being required to undergo a form of IRB review.
“The Categories” – When It’s Not So Obvious

- To those not familiar with regulation, this information may seem to be an exercise about **SEMANTICS** (the study of meaning).

- **SIMILAR ≠ IDENTICAL**
Is it research?

Is it Human Subject Research?

or

Is it *Non* Human Subject Research?
GENERALIZABLE KNOWLEDGE

- Per Federal regulations (45CFR46.102(d)):

  Research is defined as the **systematic investigation**, including research development, testing and evaluation, *designed to develop or contribute to generalizable knowledge*
Systematic investigation – refers to an activity that involves a prospective research plan which incorporates data collection and data analysis to answer a research question.

A critical factor is the primary intent (design) of the activity.
Contributing to generalizable knowledge means that:

1) Conclusions are drawn from particular instances, and

2) the information from the investigation is to be disseminated.
Some examples of dissemination:

- Doctoral thesis or dissertation conducted to meet the requirements of a graduate degree
- Presentation at a scientific meeting or conference
- Submission to or publication in a scientific journal.
Is it Human Subject Research?
(Does the Activity Involve Human Subjects?)

- Certain research does not meet the definition of human subjects research, and therefore, does not require review and approval of an IRB.

- This should **NOT** be confused with the **determination** of NHSR which **DOES** require submission to the IRB.
Non-Human Subject Research (NHSR)

- NHSR usually involves projects that involve medical record review or human tissue & specimens.

- Research that involves collection of data from the medical records or tissue of patients no longer living does not require IRB approval.

- There are a series of questions that must be asked. (Human Subject Regulations Decision Charts.mht)
WHAT IS A HUMAN SUBJECT?

Per Federal regulations (45CFR46.102(f)), a human subject is defined as:

- A *living individual* about whom an investigator (whether professional or student) conducting research obtains:
  - Data through *intervention or interaction* with the individual, or
  - *Identifiable private information*
INDIVIDUALLY IDENTIFIABLE?

- Individually identifiable, as it pertains to research involving human subjects

- defined in 46.102 – the identity of the subject is or may be readily ascertained by the investigator or readily associated with the information

- OHRP generally considers private information or specimens to be individually identifiable when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems
WHAT MAKES INFORMATION PRIVATE?

- defined in **45CFR46.102**:
  - 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)
If your activity is research but does not involve human subjects, as defined in the regulations, your activity does not fall under the purview of the IRB and you would receive an **NHSR** Determination.
Preventing infection is in our hands

THINK CLEAN PERFORM HAND HYGIENE
Types of Review

The regulations recognize three (3) review categories:

- **Exempt**
  - Must meet certain criteria
  - Differs from “Not Human Subjects Research” (designation made by IRB)

- **Expedited**
  - Must meet certain criteria
  - Does not mean “fast”
  - Reviewed by Chair and/or Designee

- **Full Board**
  - Reviewed by fully convened Board
It is important to understand that FDA regulations for the protection of human subjects do not have categories of research that qualify for exempt status like those listed by DHHS.

The FDA does not exempt any research from IRB review under its jurisdiction except in emergency circumstances and in taste and food quality studies.
May the Research Be Exempt from IRB Review?

In order to exempt research involving the collection or study of *existing* data, documents, or records from IRB review, the information must be recorded in a de-identified manner.
What is Exempt Research?

- It is implicit within the concept of exempt research that there must be very little, if any, associated risk.
- Research involving prisoners, pregnant women, fetuses, and human in vitro fertilization is **NOT** exempt.
- There are six (6) categories of research that may qualify for exempt status.
Six (6) Exempt Categories

1. Normal Educational Practices and Settings

2. Anonymous Educational Tests, Surveys, Interviews, or Observations

3. Identifiable Subjects in Special Circumstances
   (an extension of Category 2, public officials)
Six (6) Exempt Categories

4. Collection or Study of *Existing* Data and Must be Totally Retrospective in nature
   
   Link: OHRP - Guidance on Research Involving Coded Private Information or Biological Specimens

5. Public Benefit or Service Programs (Medicaid, SSI, Unemployment, Welfare)

6. Taste and Food Evaluation and Acceptance Studies
Expedited Review

- A type of review that can be conducted by the IRB Chair or designee.
- Reviewers are empowered to approve research qualifying for expedited review, or to require modifications of a study to gain approval.
- Disapproval of any research reviewed by the expedited method is prohibited, and requires the “proposed disapprovals” be referred to the full board.
- Research approved by the expedited method must be communicated to the full board.
Two (2) general groupings:

- Research activities that present no more than minimal risk or insignificant risk
  - Minimal risk – determined to be relative to the daily life of a normal, healthy person.
- Minor changes in previously approved research during the period (of one year or less) for which approval is granted.
- There are nine (9) categories of research that qualify for expedited review.
EXPEDITED - EXAMPLES

- Surveys that include identifiable information
- Interviews
- Analysis of data collected (or that will be collected) for non-research purposes
- Secondary data analysis
- Video or audio recordings
- Focus Groups
In Conclusion

1. A major point in the regulation = whether information is being collected for research or non-research purposes.

2. The defining characteristic of research is that a fundamental goal of the activity is to learn something (test a hypothesis) that will benefit people other than today’s research subjects.

3. Some research projects simply do not warrant review by the full IRB and, ideally, decreases IRB turnaround time. Nevertheless, the same regulatory and ethically based standards apply.
4. Research involving a human subject must be reviewed by an IRB if private information is recorded in a manner that is individually identifiable with specific research subjects.

5. Research should not be exempt from IRB review if study data are linked to identifying information at any point in records created by the researcher.

6. Correct application of the exempt categories can be one of the most difficult tasks facing the IRB staff.
QUESTIONS ?