“THE CATEGORIES”

When It’s Not So Obvious

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“THE CATEGORIES” - WHEN IT’S NOT SO OBVIOUS

- This information may seem to be an exercise in SEMANTICS (the study of meaning)

- SIMILAR ≠ IDENTICAL

- RESEARCH is serious business and a series of (?) must be asked.
WHAT TO ASK?

1. Is it Research?
2. Is it Human Subject Research?
   or
3. Is it Non Human Subject Research?
IS IT RESEARCH?

- 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**: An activity that involves a:

- **prospective research plan** which incorporates
- **data collection** and
- **data analysis** to answer a **research question**
Contributing to generalizable knowledge means that:

1. Conclusions are drawn from particular instances

2. The information from the investigation is to be disseminated
EXAMPLES OF DISSEMINATION

- Submission to or publication in a scientific journal

- Presentation at a scientific meeting or conference

- Student thesis or dissertation conducted to meet the requirements of a degree
• IS IT RESEARCH?

• IS IT HUMAN SUBJECT RESEARCH?
IS IT HUMAN SUBJECT RESEARCH?
(DOES THE ACTIVITY INVOLVE HUMAN SUBJECTS)

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
- Identifiable private information
Individually identifiable... As defined in 45CFR46.102:

- When the identity of the subject is or may be readily ascertained by the investigator, or
- May be readily associated with the information

When specimens can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.
Private... As 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 (i.e., a medical record)
IS IT RESEARCH? = YES

IS IT HUMAN SUBJECT RESEARCH? = YES
TYPES OF IRB REVIEW
THE REGULATIONS RECOGNIZE THREE (3) REVIEW CATEGORIES

- Full Board
- Expedited
- Exempt
TYPES OF IRB REVIEW
THE REGULATIONS RECOGNIZE THREE (3) REVIEW CATEGORIES

- **Full Board**
  - Reviewed by fully convened Board

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

- **Exempt**
  - Must meet certain criteria
  - Differs from “Not Human Subjects Research” (designation made by a delegated entity (usually an IRB))
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 (i.e., by being listed on the agenda of the next Board meeting).
EXPEDITED REVIEW, CONT.

- Two general groupings:
  - Research activities that present no more than minimal 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* categories of research that qualify for expedited review.
EXPEDITED REVIEW CATEGORIES

1. Clinical studies of drugs and devices that do not require an IND or IDE

2. Research that collects blood samples by finger stick, heel stick, ear stick or venipuncture from healthy, non-pregnant adults and sometimes children *limited amount of blood*

3. Prospective non-invasive collection of biological specimens for research purposes only

4. Collection of data through non-invasive standard of care procedures
5. Review of data, documents, records, specimens that have been or will be collected solely for non research purposes

6. Collection of data from voice, video, digital or image recordings for research purposes

7. Research performed on individual or group characteristics or behaviors or involves employing surveys, interviews, oral histories, focus groups, etc.

Categories 8 & 9 are used for research previously approved as greater than minimal risk by a full Board (continuing reviews)
Continuing review of research previously approved by the convened IRB as follows:

- Where the research is permanently closed to the enrollment of new subjects
- All subjects have completed all research-related interventions; and
- The research remains active only for long-term follow-up of subjects

Or

- Where no subjects have been enrolled and no additional risks have been identified

Or

- Where the remaining research activities are limited to data analysis.
EXPEDITED REVIEW CATEGORIES, CONT.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two through eight do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
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
- For **taste and food quality** studies
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)

4. Collection or study of existing data - must be totally retrospective in nature

5. Public benefit or service programs (Medicaid, SSI, Unemployment, Welfare)

6. Taste and food evaluation and acceptance studies
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?

- Must be very little, if any, associated risk.

- Research involving prisoners, pregnant women, fetuses, and human invitro fertilization is **NOT** exempt.

- There are six categories of research that may qualify for exempt status.
LASTLY, WHAT IF...

IS IT RESEARCH? = YES

IS IT HUMAN SUBJECT RESEARCH? = NO
REMEMBER QUESTION #3?

IS IT NON HUMAN SUBJECT RESEARCH?
NON HUMAN SUBJECT RESEARCH

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

- This should **NOT** however, be confused with the determination of NHSR which **DOES** require submission to an IRB or other entity.

- Investigators should not be given the authority to make an independent determination that their own research is NHSR or exempt.
NON HUMAN SUBJECT RESEARCH, CONT.

- **NHSR** usually involves projects that involve:
  - De-identified data sets or de-identified tissue samples
  - Collection of data from the medical records or tissue of subjects *no longer living*.

- There are a series of questions that must be asked.
  
  [http://www.hhs.gov/ohrp/policy/checklists/decision charts.html#c2](http://www.hhs.gov/ohrp/policy/checklists/decision charts.html#c2)
1. Is the information 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. 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.
IN CONCLUSION...

4. 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.

5. All human subject research must undergo IRB review via Full Board, Expedited, or Exempt procedures.

6. Certain research does not meet the definition of human subjects research, and therefore, does NOT require review and approval of an IRB.
REMEMBER WHAT TO ASK????

1. Is it Research?
2. Is it Human Subject Research?
   or
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RESOURCES

- Human Subject Regulations Decision Charts

- Definitions - 45CFR46.102

- Expedited Categories of Research - OHRP
  [http://www.hhs.gov/ohrp/policy/expedited98.html](http://www.hhs.gov/ohrp/policy/expedited98.html)

- OHRP - Guidance on Research Involving Coded Private Information or Biological Specimens

- USF IRB HRPP Policies