

# Program Evaluation Student Research & IRB Review

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# Program Evaluation

- Systematic collection and analysis of information about the effectiveness of a program in order to make judgments about the program, improve program effectiveness, and/or inform decisions about future program development.
- Involves various methods such as surveys, interviews, and the analysis of documents and background information.
- Often involves gathering information from or about human beings.
- Does it need IRB review?

# Student Research

- Research projects designed to train students in research methods
- Independent study, theses and dissertations involving research
- Does it need IRB review?

# IRB Review

Under federal regulations, all human subjects research that is not exempt from the regulations requires review by the IRB.

*What Is Human  
Subjects Research?*

# Definitions

46.102(d) & (f)

- Research - a systematic investigation designed to develop or contribute to generalizable knowledge.

# Definitions

A “**systematic investigation**” is an activity that involves a prospective research plan which incorporates data collection, ~~both quantitative and~~ qualitative, and data analysis to answer a research question.

# Definitions

Investigations designed to develop or contribute to **generalizable knowledge** are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

# Definitions

46.102(d) & (f)

- Human Subject - a living individual about whom an investigator conducting research obtains
  - data through intervention or interaction with the individual, or
  - identifiable private information

# Identifiable Private Information

- Private information - 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).
- Identifiable information – information where the **identity of the subject is or may readily be ascertained** by the investigator or associated with the information.

# *Program Evaluation*

# Program Evaluation Activities

- Program evaluation activities often involve a systematic investigation similar to research

## **BUT**

- Program evaluation activities are usually undertaken to assess the effectiveness of a specific program, practice or service

# Program Evaluation Activities

## **SO**

- Program evaluation activities are not generally considered contributing to generalizable knowledge and doesn't need IRB review

## **BUT**

- If the information from the activity is going to be generalized to other programs, then it is human subjects research and needs IRB review

# *Student Research*

# Student Research

- Student research projects often involve a systematic investigation similar to research

**BUT**

- Student research activities are usually undertaken to train students not to contribute to generalizable knowledge

**SO**

- The federal regulations don't require IRB review of student research projects

# Student Research

## **BUT**

- If the information from the activity is going to contribute generalizable knowledge (e.g. presented at a conference, published), then it is human subjects research and needs IRB review

## **NOTE**

- Theses and dissertations are always considered published

# Other Oversight

- Program evaluation activities and student research projects do have ethical issues
  - Risks to participants
  - Privacy & Confidentiality
- Institutions need to establish appropriate oversight over program evaluation activities and student research projects

# Student Research Review Models

- IRB Review
  - Umbrella protocols submitted by instructor
- Departmental Review
- Student IRBs

# Secondary Use

- What if
  - A program evaluation activity or student research was not approved by the IRB
  - Results are interesting and should be shared
- Does that mean that the results cannot be shared?

# Secondary Use

- Can be submitted to the IRB as secondary use of existing data
- Expedited Review Category #5
  - Research involving materials (data, documents, records, or specimens) that **have been collected, or will be collected solely for nonresearch purposes**
- IRB needs to evaluate whether it is an appropriate use and can waive informed consent
- Need to be sure not being used as loophole to avoid prior IRB review

# Summary

- Program evaluation and student research usually do not meet the definition of human subjects research
- Program evaluation and some student research do not require IRB review under the regulations
- Program evaluation and student research projects need ethical oversight
- Results can be used for research with appropriate IRB review