Program Evaluation & 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?
IRB Review

Under federal regulations, all human subjects research that is not exempt from the regulations requires review by the IRB.
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Is Program Evaluation Human Subjects Research?
Definitions

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

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Definitions

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

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

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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
Other Oversight

- Program evaluation activities do have ethical issues
  - Risks to participants
  - Privacy & Confidentiality
- Institutions need to establish appropriate oversight over program evaluation activities
Secondary Use

- What if
  - A program evaluation activity was not approved by the IRB
  - Results are interesting and would benefit other programs

- 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 is like research but usually does not meet the definition of human subjects research
- Program evaluation usually does not require IRB review
- Program evaluation needs ethical oversight
- Results can be used for research with appropriate IRB review