

Program Evaluation & IRB Review

Jeffrey M. Cohen, Ph.D. CIP
President
HRP Associates, Inc.

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.

IRB Review

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



*Is Program Evaluation
Human Subjects
Research?*

Definitions

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

Definitions

- 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

- 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

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

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

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

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**

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