



# IRB Toolbox

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## Program Evaluation: When is it Research?

Researchers are often confused about the need for Institutional Review Board review of program evaluation projects. What is program evaluation? The Center for Disease Control defines it as *the systematic collection of information about the activities, characteristics and outcomes of programs to make judgments about the program, improve program effectiveness, and/or inform decisions about future program development.*

When questioning if your program evaluation project needs IRB review the researcher should ask: Does the project meet the definition of research as defined in the human subject protection regulations? That is, is it a *systematic investigation, including research development, testing and evaluation designed to contribute to generalizable knowledge?*

Program evaluation activities are not considered human subject research when:

- They do not involve experimental or non-standard interventions;
- Their intent is only to provide information for and about the setting in which they are conducted;
- They are conducted as part of the standard operating procedures of the setting; and
- They are (usually) not subject to peer review.

Some questions you can ask to help with these decisions:

- Is the goal of the program evaluation to test a hypothesis or answer a research question? If **no**, the activity is probably not research.
- Will the activity benefit people or communities or entities other than those from whom the data are collected? If **no**, the activity is probably not research.
- Is the activity a routine operation in the setting? If **yes**, the activity is probably not research.
- Do the data gatherers have regular and routine contact with the data or the subjects? If **yes**, the activity is probably not research.
- Does the activity alter the timing or frequency of standard procedures? If **no**, the activity is probably not research.
- Is the entity in which the activity is taking place paying for it? If **yes**, the activity is probably not research.
- Is the activity part of a research project? If **yes**, the activity probably **is** research.

The IRB recommends making the decision regarding review of your program evaluation project in concert with the IRB, either through discussions or via submission of the Determination of Non-Human Subject or Non-Research Form. For assistance, please call or come by the IRB office located in the Office of University Research Compliance, 219 Cordell North, 405.744.1676.



