



Why should evaluators care about research ethics?

Amy Donovan, PhD, CIP

Partner at Solutions IRB

As a private Institutional Review Board (IRB), we see a significant number of submissions from program evaluators, consultants, and evaluation research organizations. These folks may be relatively new to working with ethics review boards; but all are eager to do the right thing by their clients or organizations, and they recognize the value of a third-party review of their evaluation, but they're not familiar with the federal regulations and might not be entirely clear on why they should care about research ethics when what they do is not typically considered research. Our goal is to provide evaluators with a series of bite-sized articles to help break down the key pieces of the human research protections regulations and show how they apply to program evaluation.

First, the basics--an IRB is an Institutional Review Board, also frequently referred to as ethics review boards or research ethics boards (REB). These boards are governed by a set of federal regulations in the Department of Health and Human Services (DHHS) Code of Federal Regulations (45 CFR 46). Most hospitals and colleges/universities have an IRB to review the research conducted within their organization. Some large school districts or other organizations that engage in a high volume of research have their own IRB, but many public and non-profit organizations rely on private IRB's because they don't have an affiliation with an institutional IRB. Solutions IRB is one of many private IRB's who provide fee-based services.

The primary goal of an IRB is to make sure research is designed to minimize risks to participants and maximize benefits to both participants and society. In many ways, the goal of an evaluator is similar, though at a higher level, evaluators strive to ensure that organizations, programs, policies, departments, or products are performing in the best way possible, ultimately to positively impact the public good. Both desire high-quality, culturally competent approaches to solving real-world problems.

Evaluation typically involves the collection of information from stakeholders. When the information collected is publicly available, or is existing information that does not identify anyone, such as in policy evaluation or the evaluation of a technology product, it doesn't involve what might be considered "participants". Often, though, information is collected from people who have experience with the program or product being evaluated. In those cases, part or all of the evaluation activities might meet the federal definition of "research".

45 CFR 46.102 defines research: “(d) *Research* means a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.”

I think we would all agree that evaluation is systematic, but is it designed to contribute to generalizable knowledge? In a 2012 research study about the state of evaluation in non-profits (<http://www.stateofevaluation.org/>), 66% of respondents indicated that they share findings from evaluation activities with non-client stakeholders. The same report indicated that 48% of respondents use their findings to share best practices and lessons-learned. This type of dissemination is typically considered a contribution to generalizable knowledge; publication of findings is not necessary for an activity to be considered research.

In order to be considered human subjects research that requires IRB review, a project must both be research (as defined above) and also involve human subjects. 45 CFR 46.102 defines human subjects: “(f) Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:(1) Data through intervention or interaction with the individual, or (2) Identifiable private information.”

So, when evaluators obtain data and information from people in their evaluation activities, they may be engaging in research with human subjects according to the federal regulations definitions. It is becoming more widely recognized that evaluation activities frequently include human subjects research. At Solutions IRB, we have seen social/behavioral and educational researchers and evaluators request IRB review as part of the process for obtaining grant funding. The National Science Foundation, for example, frequently requires documentation of IRB approval before dispersing (or: the dispersal of) grant funds.

While some evaluators are seeking IRB review because it’s a funding requirement, we also see many evaluators who recognize that IRB review, and the understanding it brings about research ethics, can make them better evaluators. IRB reviewers look at things from a different lens and their input, direction, and engagement can add to the knowledge base of evaluators to better protect the people in programs they evaluate.

Over the coming weeks, be on the lookout for articles on privacy and confidentiality, informed consent, internet research, and research with vulnerable populations. If we’ve really piqued your interest, you can learn much more about this topic at www.solutionsinstitute.com .