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What Cooperative Extension Professionals Need to Know About Institutional Review Boards: Risks and Benefits

Dan Weigel *University of Nevada, Reno*, weigeld@unce.unr.edu

Sally Martin *University of Nevada, Reno*, smartin@unr.nevada.edu

Randy Brown Brown & Associates Research, brownr@unce.unr.edu



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What Cooperative Extension Professionals Need to Know About Institutional Review Boards: Risks and Benefits

Abstract

More and more, Extension professionals are being asked to first run their needs assessment, program evaluation, and applied research projects through their university's Institutional Review Boards. For many, this can be a confusing task. This article is the third in a series providing tips for preparing IRB proposals and discusses the potential risks and benefits involved in research projects.

Dan Weigel

Area Extension Specialist/Professor University of Nevada Cooperative Extension University of Nevada, Reno Reno, Nevada weigeld@unce.unr.edu

Sally Martin

State Specialist/Professor **Human Development and Family Studies** University of Nevada, Reno Reno, Nevada smartin@unr.nevada.edu

Randy Brown

Consultant Brown & Associates Research Hollister, California

brownr@unce.unr.edu

More and more, Extension professionals are being asked to first run their needs assessment, program evaluation, and applied research projects through their university's Institutional Review Boards (IRBs). This article is the third in a series that addresses a number of issues in working with IRBs. (See "What Cooperative Extension Professionals Need to Know About Institutional Review Boards" and "What Cooperative Extension Professionals Need to Know About Institutional Review Boards: Recruiting Participants".) This article concerns the issues of risks and benefits associated with a research project.

What IRBs Look For

As IRBs review proposals, their primary concern is the protection of the rights and welfare of human subjects in research. The efforts of IRBs are directed at:

- Identifying the risks associated with the research;
- Evaluating procedures to minimize risk;
- Identifying the potential benefits to be derived from the research;
- Determining whether the risks are reasonable in relation to the benefits to subjects, if any, and assessing the importance of the knowledge to be gained; and
- · Ensuring that potential subjects will be provided with an accurate and fair description of the

risks or discomforts and the anticipated benefits.

Why is it important to consider the risks and benefits to participants? For potential participants to make a truly informed decision, they need to be able to weigh what risks they may encounter versus what benefits will come from their participation. In making their assessment, the IRB takes into account the purposes of the research and the setting in which the research will be conducted.

Identifying Risks

When writing a protocol, it is important for Extension professionals to thoroughly consider the potential risks that participants may encounter. There are several types of risks.

Physical Risk

Is there a chance that participants can be physically hurt or injured by participating in the project? For example, the evaluation of an educational nutrition and health project might include measures of body fat or the collection of blood or other bodily fluid. How might the collection of such data be risky for participants?

Emotional Risk

Does the collection of information generate emotional distress or anxiety? In an evaluation of a parent education program, for instance, are questions being asked that may create a strong sense of inadequacy or quilt in young parents?

Social Risk

Does participating in the evaluation or research project create a risk of affecting people's relationships with family, friends, neighbors, or other community members? For example, if it becomes known that a farm operator is participating in an Extension program designed to help farmers on the verge of foreclosure, how could that influence his or her relationships with friends, neighbors, or even potential lenders?

Economic Risk

Can participants be financially affected in a research project? An economic business development project in a small, rural community, for instance, might ask business owners to disclose financial information or business practices. If such information becomes known in a small town, it could jeopardize the future of that business.

Legal Risk

Are participants being asked to reveal information that might put them at risk for legal action? For example, a community-wide survey of youth might ask questions about implicating or illegal behavior, such as drug use, criminal activity, or sexual behavior. If a specific teenager's answers become known, the information might become grounds for criminal procedures.

Minimizing Risks

Just as important as identifying potential risks, IRBs look for safeguards that are in place to minimize potential risks and protect people's privacy and confidentiality. They look to see that risks are minimized as much as possible by:

- Using procedures that do not unnecessarily expose participants to risk;
- Determining if appropriate additional safeguards are in place to protect the rights and welfare
 of subjects, especially if they are likely to be members of a vulnerable population (e.g.,
 children, prisoners, fetuses, pregnant women, human in vitro fertilization, persons who are
 cognitively impaired, or persons who are economically or educationally disadvantaged); and
- Determining whether adequate procedures are in place to protect the privacy of subjects and to maintain the confidentiality of the data.

Identifying Benefits

Beyond assessing risks, IRBs look for what benefits might come from the research project for participants, if any, and for the field in general. For example, an Extension professional might evaluate two exercise programs for senior citizens. If participants were to receive a summary of the results and be able to enroll in the better program, they may have direct benefits resulting from the study.

In addition to benefits for participants, some of the benefits for the field in general might include the identification of promising techniques for identifying needs, the recognition of effective teaching strategies or technologies, or the highlighting of educational programs that truly make a difference in people's lives. If results of the evaluation of the exercise program were to be shared at conferences or in publications and used in future programming, then the study may advance the field in general.

Comparing Risks and Benefits

In their discussions, IRBs weigh whether the risks to participants are reasonable in relation to anticipated benefits. The goal is to ensure that the risks to research participants posed by participation are justified by the anticipated benefits to the participants or society. Toward that end, IRBs judge whether the anticipated benefit, either of new knowledge or of improved well-being for the research participants, justifies asking any person to undertake the risks.

Communicating Risks and Benefits to Participants

IRBs will want to see how the Extension professionals plan to inform potential participants of the risks and benefits. Projects can have risks, but those risks need to be communicated so participants can make an informed decision about whether or not to participate.

Obtaining informed consent is a critical step in conducting ethical research projects. As part of that consent process, people need to know what risks might be involved and what benefits might result from their involvement--only then can they make an informed choice to participate. The final article in this series will focus more closely on the issue of obtaining informed consent.

In conclusion, as Extension professionals plan their projects, they will want to keep in mind the potential risks and benefits for participants. Addressing these issues will make for a better IRB submission and ultimately higher quality projects.

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