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What Cooperative Extension Professionals Need to Know About Institutional Review Boards: Obtaining Consent

Abstract
This article focuses on the process and forms used to obtain consent from people who might participate in a needs assessment, evaluation, or research project designed for presentation or publication. It is the fourth in a series providing tips for preparation of IRB proposals by Extension professionals.

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This is the fourth in a series of articles designed to help Extension professionals who need to go through their university's Institutional Review Board (IRB). (See "What Cooperative Extension Professionals Need to Know About Institutional Review Boards," "What Cooperative Extension Professionals Need to Know About Institutional Review Boards: Recruiting Participants," and "What Cooperative Extension Professionals Need to Know About Institutional Review Boards: Risks and Benefits.")

In this article we focus on obtaining consent to participate in a study, including the process, the consent forms, active and passive consent, special populations, and a waiver of consent.

The main purpose of consent is to explain the study to potential participants so that they can make a *fully informed* and *voluntary choice* to participate. The process for obtaining consent must be described in the IRB protocol, including how, when, and where consent will be obtained.

What IRB's Look For

- Are any verbal or written explanations at an appropriate educational level and in the primary language of the potential participant? Will someone from the research team be available to explain the project and answer questions in the language of the participants? Is lay language used in both verbal and written explanations? For example, consider the statement "We are studying the efficacy of two program modalities on child outcomes." Although perfectly accurate, the average person may have no idea what this study is about. A clearer explanation might be, "We are studying whether children learn more when they participate in regular 4-H clubs or when they belong to special 4-H programs that only meet over the Internet."

- Will potential participants know that they do not have to volunteer for the study and can withdraw at any time? Will they understand that they can skip questions in an interview or on a survey? Extension professionals working with young children may need to describe how they will determine when the child wishes to withdraw. For example, suppose a preschooler clings to the caregiver or cries when the data collector asks questions? Is this a signal that data collection should be postponed or stopped?

- Will consent be sought in a group setting where potential participants may feel pressure to volunteer? Maintaining confidentiality about who provides consent is important to avoid such influences. One way to do this is to provide two consent forms in a large envelope (one to keep and the other to turn in) and ask everyone in the group to return one consent form in the envelope (signed or not, or marked "yes" or "no").

- If studies have several parts or involve videotaping, can people consent to participate in one but not the other? IRB's often require two documents if the study involves both an assessment exercise and videotaping of participants. That way, participants can agree to be in the study but not to be videotaped.

Informed Consent Document

In most cases, each potential participant is given a written consent form explaining the project. The IRB will look for the following elements:

- Statement of purpose that explains that the project involves research;

- How long the study will last and how much time it will take;

- Procedures that will be followed;

- Foreseeable risks or discomforts as well as potential benefits to the participant or others (There may be no direct benefit to participants.);

- How confidentiality will be maintained, including the identity of participants and the information they provide;

- If and how compensation will be provided as well as any costs to the participant;

- A statement that participation is voluntary, that there are no penalties for deciding not to participate, and that individuals may stop participating at any time or choose to skip questions (IRB's may ask if Web-based surveys are designed so that participants can skip a question and still be able to move on to the next one.);

- A statement that any new findings that might relate to a participant's willingness to participate would be provided and a new consent would be obtained;

- Information about the specific office, names and contact information for members of the research team and, usually, how to contact the institution's IRB office, anonymously if desired; and

- Resources for subjects who become distressed by the project, for example, a list of mental health professionals for farmers answering questions about the impact of losing their farms would be appropriate.

For Extension professionals evaluating programs, it is important to focus on the purpose, procedures, and costs/benefits of the evaluation rather than the program. Many IRB members are not familiar with community education and can confuse the program that you would be conducting anyway with the evaluation, for which you need IRB approval.

Active and Passive Consent

Many Extension professionals conduct studies with children that require consent from parents or legal guardians. *Passive* consent procedures inform parents about and describe the research. Parents sign and return the form or contact an investigator if they do **not** want their child to participate. Passive consent may be allowed if there is no risk to participants, the questions being asked are not sensitive, and the children are adolescents capable of making decisions about participation. Typically, the response rate is better and results are more generalizable when passive consent is acceptable.

More commonly, *active* consent is required. That is, parents or legal guardians must sign and return a consent form granting permission for their child to participate. For helpful articles on increasing the response rate when active consent must be obtained, see Fletcher and Hunter (2003), Iverson and Cook (1994), and MacGregor and McNamara (1995).

Assent

Although children cannot legally give consent, Extension professionals studying children usually

need to gain assent from them. In the protocol, investigators should describe the assent process. The IRB will assess: 1) how the study will be explained to children, 2) if children will feel they can say no, and 3) if children can change their minds during the study and withdraw.

Each IRB sets policies regarding the age at which children are to be given Assent Forms; at our institution, children ages eight and older receive such documents. These are parallel to Consent Forms for adults and include a place for the child to sign, but they are written in simple language easily understood by children. For example, an Assent Form could say, "You don't have to be in this study. Even if you agree to be in the study now, you can change your mind later. Your leader will not be mad at you if you do not want to be in the study."

Other Vulnerable Populations

When potential participants have cognitive or communicative limitations, consent from a legal guardian is typically required. Special care must be taken to avoid coercion in obtaining consent from other vulnerable populations, such as prisoners, youth whose leaders are collecting data, or individuals with serious health concerns who are highly motivated to get Extension services.

Waiving Consent

A signed consent document is not always needed. Extension professionals may apply for a waiver of consent if:

- The research involves no more risk than participants would typically encounter in daily life;
- The waiver would not negatively affect the welfare of participants.;
- The research could not be carried out without the waiver; and
- Participants will be provided with information after participation if deception is involved.

Although preparing an IRB protocol can be challenging, Extension professionals often have exceptional skills in presenting complex information in simple, straightforward language. Such skills are helpful in explaining the process and preparing consent and assent documents. We hope that this article and the others in the series will help you through the IRB process.

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