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What Cooperative Extension Professionals Need to Know About Institutional Review Boards

Abstract
Increasingly, Cooperative Extension professionals are required to have their projects approved by their university Institutional Review Boards. For many, this can be an intimidating task. In this article we provide information that we hope will help ease the confusion and frustration that can sometimes accompany the process. We also present several tips for helping the process go more smoothly.

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Have you ever struggled writing a proposal to your university's Institutional Review Board (IRB)? If so, you are not alone. Increasingly, Cooperative Extension professionals are expected to collect, present, or publish data about community needs, programming effectiveness, and applied research projects. Often, Extension professionals are gathering information from or about people, and such research or evaluation projects must be approved by a university's IRB.

While some Extension professionals may have considerable experience with IRBs, others may lack understanding or struggle with particular issues that are involved in the IRB process. This article is the first in a four-part series designed to help Extension professionals better understand the purpose and procedures of Institutional Review Boards (IRBs). We hope to ease the confusion and frustration that can sometimes accompany the IRB process.

What Is an IRB?

An IRB is a review committee established to help protect the rights and welfare of human research subjects. The basic purpose of the IRB is to provide oversight to research that involves collecting data and information from or about people. The information might involve input from community members, ranchers and farmers, 4-H'ers, seniors, and so forth. Basically, the IRB is there to help ensure that when university-affiliated personnel work with people and collect information from them, it is conducted in an ethical way.

IRBs are federally mandated committees. Federal regulations specify that institutions that engage in research, such as universities, must establish IRBs to oversee research involving human subjects. IRBs are composed of members from various colleges on campus as well as community

members whose expertise is valuable in the review process. In some cases, Cooperative Extension personnel serve on the committees. The authors, who are Extension professionals, have a combined 19 years of experience serving on IRBs.

How Cooperative Extension and IRBs Interact

Cooperative Extension is part of a university system and therefore falls under the same research policies and guidelines as other university units. Typically, if an Extension professional intends to publish or present the information gathered in the form of journal articles, trade articles, bulletins, fact sheets, workshops, or presentations, the project should first be approved by the IRB at the professional's institution. Information collected with no intent to publish it and used merely to evaluate the effectiveness of a program is usually not required to be reviewed by an IRB.

Benefits of Working with IRBs

Despite what can sometime appear as an aggravation, there are advantages to working with IRBs.

- Typically, going through the IRB process makes for a better project. An Extension professional can take advantage of the expertise of a wide variety of researchers who might provide important and useful suggestions that will improve the quality of information collected.
- Working with an IRB can provide a researcher with confirmation that he or she is treating participants ethically and responsibly.
- Going through the IRB process also protects the researcher. Having obtained IRB approval means that the university approves the project. In case something unforeseen and/or dangerous happens during a project, as long as the research was proceeding ethically and following the approved procedures, the IRB and university are responsible rather than the individual researcher.

What Is Needed to Apply for IRB Approval?

Although IRBs develop their own application forms, there are key elements common to all committees. It is important to keep in mind that the primary focus of the IRB review is the protection of human subjects, not the rigor of the research design, per se. Applications should address the following elements.

- A brief summary of the rationale or purpose of the research.
- A plan for how participants will be recruited that is not coercive and that provides participants with enough information to make an informed and voluntary choice.
- A plan for obtaining informed consent (or assent from minors or decisionally impaired individuals) from participants before they agree to become involved in a project.
- A detailed plan for how data is going to be collected, stored, and analyzed.
- If the research involves an individual participating in a program, intervention, or some kind of activity that is being evaluated, a description of the activity.
- An identification and analysis of the risks to people participating in the research project and of ways that the risks will be minimized.
- An identification of benefits for participants, if any, and for the field in general.
- An indication of what safeguards are in place to minimize potential risks and protect people's privacy and confidentiality.

How Can You Help the Process Go Smoothly?

Based on the authors' experiences both serving on IRBs and shepherding proposals through the process, some steps can help the process go more smoothly.

- Find out about the specific guidelines and policies of your university's IRB. IRBs are mandated to have specific policies in place, and most often these guidelines can be found on IRBs informational Web pages. Following these guidelines in preparing your protocol can save you headaches down the road.
- Talk to people who are currently on the committee or recently have served on it. They should be able to give you some tips on writing your proposal and on potential red flags to avoid.
- Talk to IRB staff about questions before sending in your final protocol. Be up front and honest about questions or delicate issues. They usually prefer this, and their suggestions can save you considerable time and effort.
- Have someone familiar with the process review your proposal. Another set of eyes can often

spot things you might have missed or areas that might need more clarification.

- Examine successful protocols, especially those from Cooperative Extension or applied projects. Ask the IRB staff if they have good examples; many have example protocols posted on their Web pages.
- Several IRBs have developed Web-based training courses on writing protocols and conducting ethical research. Completion of these courses has become a requirement at many institutions before someone can have a protocol approved.
- Make sure your protocol has addressed all of the necessary elements specified in the IRB guidelines. Many applications are returned because of insufficient information and detail.
- Do not assume that members of the IRB understand Extension or community education or the terminology common to your field. Be sure to use descriptive language that someone with no previous knowledge of your work can understand.
- If you intend to evaluate a program, clearly separate the program from the research/evaluation component. If people can participate in the program without volunteering for the evaluation component, clearly explain this option.
- Plan ahead, and be patient. After the initial review, the IRB often asks for clarification or requests that you make changes in your protocol that must be submitted before final approval. Many committees only meet once or twice a month, so be sure to give yourself enough time to obtain approval before you intend to start collecting data.
- Remember that obtaining IRB approval is a learning process. Each time you go through the IRB process you will be better prepared for the next time.

We hope that this article provides some background and explanation about the IRB process. Future articles in this series will address in greater detail: recruiting participants and vulnerable audiences, addressing risks and benefits, and handling informed consent and confidentiality.