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What Cooperative Extension Professionals Need to Know About Institutional Review Boards: Working with Youth

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Abstract: University Institutional Review Boards (IRB) carry the responsibility of reviewing and approving all research protocols involving human subjects. As Extension professionals prepare to assess the effectiveness of 4-H and other Extension youth programs, they should be aware of the general requirements imposed by IRBs and particularly of the special requirements for research involving youth. In this article, we outline the IRB requirements often applied to youth research and provide tips for Extension professionals involved in such projects.

Introduction

A number of articles have appeared in *JOE* regarding laws and regulations associated with research on human subjects and the subsequent challenges of working with Institutional Review Boards (IRB). Weigel, Brown, and Martin (2004) provided a general overview of IRB rules and regulations. Later articles addressed specific issues about IRB requirements and human subject research, including obtaining consent (Martin, Weigel, & Brown, 2004), recruiting participants (Brown, Martin, & Weigel, 2004), managing risk (Weigel, Martin, & Brown, 2005), working with multiple IRBs (Betts, Peterson, & McDonald, 2005), and working with Native American IRBs (McDonald, Peterson, & Betts, 2005). Although these articles collectively provide an excellent overview of IRB requirements and procedures, they don't fully address one particularly difficult facet of research on human subjects: working with youth.

As more scrutiny is placed on the effectiveness of Extension programs and competition increases from other extra-curricular youth programs, Extension Professionals will be required to better evaluate the effectiveness of 4-H and other Extension youth programs. As such, more and more Extension Professionals will likely be involved with youth research, but they must recognize that youth have special legal protections, which makes

research with them particularly challenging.

We have recently initiated a study to evaluate an educational program in high school classrooms. Although we had significant experience with research involving adults and subsequent IRB requirements, we were surprised and unprepared for the level of scrutiny directed at youth research. In this article, we share what we learned to help others avoid some of the surprises we experienced.

Consent

The purpose of consent is to explain the study to potential participants and allow them the prerogative to make an informed and voluntary decision about whether to participate. Obtaining consent is the primary differentiator in IRB requirements between adult and youth research, and it can be quite an obstacle in youth research. As Martin et al. (2005) point out, minors cannot concede to participation in research; that responsibility falls to their parents. However, in obtaining approval for our youth study, we realized the IRB had additional consent requirements for studies involving youth in school settings. The following outlines the forms of consent often required for research involving minors.

Active Parental Consent

Active consent is typically required for research using minors. In this case, parents receive information regarding the research and must consent allowing the child to participate. Most universities have templates and example forms illustrating the information required for a parental informed consent form. In rare cases, however, when the research is collectively considered harmless, Passive Parental Consent—where parents' consent is assumed unless they actively choose otherwise—may be allowed.

Informed Assent

If a research subject is under the age of 18, but can understand research protocol and willingly participate in a study, the IRB will require the minors involved to assent, that is, agree willingly to participate in the study. Assent forms should be worded simply, using phrases and words appropriate to the age and educational level of the minors involved.

Teacher Consent

When research takes place during class session and involves the classroom teacher, IRB also requires the teacher to consent. This consent form notifies IRB and parents that teachers are aware of the research objectives, their role in the research, and their responsibilities to the researchers. In addition, it outlines their rights to discontinue the research if ethical and satisfactory research conditions are not upheld.

School Consent

IRB also requires that the school where the research is conducted provide consent. In a public school, consent must come from the Superintendent; in a private school, consent from the Principal or Head Master is required. Herein lies much of the frustration of youth research in schools, because little standardization exists between school districts regarding youth research. In some cases, the Superintendent can grant consent, but other districts may require detailed evaluations of the research by a curriculum coordinator or even the entire school board. In any case, the following recommendations will increase chances for school district approval, especially when working with schools that are not in your area or where you do not have contacts:

- Prior to requesting a signature on a consent form, make contact with the school district to ask what their requirements for research within the school district may be. If an application for research is required in addition to the consent form, ask for an application and have it filled out before you contact the Superintendent or Principal.

- Outline any risk that may be posed to students, including sensitive questions or research materials. Explain any risks in detail and allow school officials to ask any relevant questions. Most importantly, explain the benefits of your research.

- Create a consent letter for the Superintendent/Principal incorporating all of the relevant information needed by IRB. Include their school or school district name, the teachers involved, the schools involved, and the research protocols. Sending a pre-worded consent document for them to sign will increase your chances of return for that school or school district. Contact your IRB administrator to discuss items that need to be included in the school district consent letter.

- Inform teachers of the necessity to obtain school district or principal approval. In some cases, they may be able to help you obtain approval by encouraging their Superintendent or Principal to grant consent.

Conclusion

Extension professionals may be skeptical of IRBs as unnecessary bureaucracy and be tempted to ignore them, but they should be aware the potential penalty for violation of IRB regulations is severe; major violations can result in a suspension of all federal funds for the institution. One also should never underestimate whether IRB approval is required for a project.

Based on our experience, IRB places tremendous scrutiny on research involving youth, and even seemingly innocuous projects may need IRB approval. A colleague of ours recently wanted to report, via presentation at a small state conference, the demographic data for youth participants at a summer 4-H camp. After inquiry, the IRB determined that such presentation would be inappropriate because they had not previously approved the data collection protocols. In short, Extension professionals should contact their IRB administrator before collecting any data involving youth.

Assessing the effectiveness of youth programs is crucial, and IRB requirements should not deter Extension professionals from conducting important research. Challenges of meeting IRB regulations can be overcome by being well informed and maintaining open communication with IRB administrators. Don't be afraid to ask questions, and most important, don't be afraid of pursuing valuable research. A great deal of useful information on youth and IRB can be found in the IRB Guidebook Chapter 6: Special Classes of Subjects <http://www.hhs.gov/ohrp/irb/irb_chapter6.htm >.

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