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More Tips: Communicating with Institutional Review Boards Over the Course of Your Project

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More Tips: Communicating with Institutional Review Boards Over the Course of Your Project

Abstract
This article focuses on the continuing review process required by Institutional Review Boards. It is a follow-up to a series of recent articles designed to help Extension Professionals navigate the university IRB process. The authors present general guidelines for the continuing review process and offer some issues and tips for success.

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Introduction

This is the third follow up to a series of four recent articles designed to help Extension Professionals navigate the university Institutional Review Board (IRB) process (Brown, Martin, & Weigel, 2004; Martin, Weigel, & Brown, 2005; Weigel, Brown, & Martin, 2004; Weigel, Martin, & Brown, 2005). The first follow up was on working with more than one IRB at a time (Betts, Peterson, & McDonald, 2005), while the second focused on working with tribal IRBs (McDonald, Peterson, & Betts, 2005). The current article focuses on the process of continuing review by IRBs.

After a project has received approval from an IRB, federal regulations require that projects be re-reviewed at regular intervals if research activities are continuing (e.g., recruiting participants, collecting and analyzing data, or paper, presentation or poster writing). This is called "continuing review." The purpose of continuing review is to ensure that the previously approved protocol has been followed, that the protections for participants are still adequate, that the anticipated benefits still justify the risks to participants, that any new regulations for human subjects research are incorporated, and that new research findings that may impact the project are considered.

We visited several university IRB Web sites to review various policies and procedures regarding continuing review. As may be expected, there were many similarities and a few differences across universities. Because all university continuing review policies are based on those developed by the Office for Human Research Protection (OHRP) within the Department of Health and Human Services (HHS), OHRP's general guidelines are presented here.

OHRP offers guidance on conducting continuing reviews of research and delineates specifically what information must be submitted for review <www.hhs.gov/ohrp/humansubjects/guidance/contrev2002.htm>. OHRP stipulates that a review be conducted at least once each year (or more frequently if there is greater risk involved), and that the following information be provided:

- A report on the total number of subjects accrued;
- A summary of any adverse events, problems, withdrawals, or complaints about the research project since the last review;
- A summary of relevant recent literature, findings, or any changes to the research since the last review;
- Any relevant multi-center trial reports (where more than one institution is involved in the research);
- Any relevant information, especially involving risks associated with the research; and
- Copies of the current consent form along with any proposed changes in the form.

While the annual review process provides a time for examining consent documents, it is important to keep in mind that during the project, whenever there is new information that requires modification of the consent form, the revised form must be approved by the IRB.

OHRP also provides some guidance on whether or not the continuing review documents need to be reviewed by all IRB members or if the IRB chair (or designated IRB member) can conduct the review (otherwise known as an "expedited review"). Generally speaking, if your research project originally qualified for expedited review, then in most circumstances it will be eligible once again unless there are changes that would no longer permit an expedited review. It is also possible for a research project to not be eligible initially for expedited review, but to qualify as expedited during the continuing review process if it meets the following criteria (taken from the Guidance on Continuing Review, July 11, 2002):

- The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or
- No subjects have been enrolled and no additional risks have been identified; or
- The remaining research activities are limited to data analysis.

There is no grace period permitted after the expiration of the annual review approval period, so you will want to make sure you have provided your information to the IRB in a timely manner, usually at least 30 days prior to the approval expiration date. The approval expiration date is determined at the time of the initial IRB review. OHRP provides a few different scenarios for IRBs to use in determining the review date, but suffice it to say that in most cases it will be one year after final approval is given at an IRB meeting (even if minor revisions are required) or after the IRB chair gives approval if an expedited review process is used.

Issues and Tips

Follow Your University's Specific Continuing Review Procedures

While general information about continuing review has been provided above, keep in mind that your university's IRB will have specific procedures that you must follow. Their guidelines will discuss the information and documents you will need to submit for continuing review. Be sure to closely follow the instructions and meet the imposed deadline to prevent approval from lapsing, resulting in a delay to your project.

Seek IRB Approval for Any Protocol Modification

IRB approval must be obtained for any changes to an already approved protocol. These changes include modifications to consent forms, participant recruiting procedures, incentives, data collection instruments or methods, or personnel. For example, if you have been previously approved to recruit participants through fliers in grocery stores, but now want to also place an ad in the newspaper, this change must first be submitted to and approved by your IRB. Although the continuing review process provides the opportunity for you to summarize any changes in one place, you must notify your IRB along the way.

Avoid Noncompliance and Misconduct

Allegations of noncompliance, or research not conducted in accordance with policy, can come to the attention of the IRB during the continuing review process. Misconduct is fabrication, falsification, plagiarism, or other practices that seriously deviate from accepted practices within the research community or a failure to disclose conflict of interests. Most researchers share goals of ethical conduct and want to comply with regulations that are there to protect the subjects and themselves. You will find that regular communication and periodic review with your institution's IRB will help you reach those goals.

Conclusion

The importance of communicating with your university's IRB cannot be overstated. By keeping the IRB informed of any changes to approved protocols or problems as they arise and by submitting requested documentation and information on a regular basis as required, you will be able to ensure a smooth-running project.

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