

On Institutional Review and Human Subjects Use or Why Do Extension Faculty Need To Make An IRB Application?

Think about the last evaluation you conducted, or that you assisted faculty to conduct. With that in mind, answer the following questions¹

- ◆ Do you plan to publish the results of the evaluation in a professional journal?
 - ◆ YES
 - ◆ NO
 - ◆ MAYBE

- ◆ Do you plan to share the results of the evaluation at state, regional, national, or international meetings?
 - ◆ YES
 - ◆ NO
 - ◆ MAYBE

- ◆ Is the evaluation a part of an internal or external grant or contract?
 - ◆ YES
 - ◆ NO
 - ◆ MAYBE

- ◆ Do the data collection processes present a situation that is minimal, or greater than minimal, risk?
 - ◆ YES
 - ◆ NO
 - ◆ MAYBE

- ◆ Does the evaluation involve sensitive topics (e.g., substance abuse, illegal activities) or use instruments that may contain sensitive data?
 - ◆ YES
 - ◆ NO
 - ◆ MAYBE

- ◆ Will data for the evaluation be collected from vulnerable subjects (youth, incarcerated individuals, and pregnant women)?
 - ◆ YES
 - ◆ NO
 - ◆ MAYBE

- ◆ Will data collection involve videotaping, audiotaping, or photography?
 - ◆ YES
 - ◆ NO
 - ◆ MAYBE

- ◆ Does the evaluation fulfill requirements of a course you are taking in a University department?
 - ◆ YES
 - ◆ NO

If you answered yes or maybe to any of the above questions, then you have the responsibility and obligation to ensure your participants that their rights as subjects in research are protected. Those assurances are confirmed through the institutional review process.

Now before you say, “I’m not doing research, I’m just evaluating my programs.” understanding what these assurances are, the history behind them, and how universities apply them may safe guard you, your participants, and your university.

Over the last three years, I have been working with the Oregon State University (OSU) Research Office to help them understand OSU Extension Service (OSU ES) program evaluation activities that involve human subjects. At the same time I have been working with OSU ES Faculty to help them understand and comply with the federal regulations related to the use of human subjects in evaluating their programs. Compliance with Federal regulations, and the evaluation research activities of faculty, are typically monitored by the university research office.

WHY DO EXTENSION FACULTY NEED TO COMPLETE AN IRB APPLICATION?

The simple answer is “Federal law requires it.” The ethical answer is “We have a responsibility and an obligation to assure our participants that their rights are protected.” Let me explain. Federal law (45 CFR 46-B) was enacted to ensure that *the rights of individuals* (in Extension that means program participants) *participating in behavioral research* (this is all the outcome program evaluations of the educational activities that Extension Faculty implement) *are maintained; that the information the participants provide remains confidential; and that the participants engage in the evaluation voluntarily.*

This legislation applies to all universities, hospitals, and other institutions conducting biomedical and behavioral research. I’ve included several hyperlinks at the end of this paper summarizing the history leading up to this legislation.

To put all of this into perspective, I’ll summarize key events leading up to the U.S. Federal legislation which affects all Extension faculty.

- ◆ In 1947, following the Nuremberg Trials which dealt with the Nazi atrocities perpetrated on the interned Jews during WWII, the Nuremberg Code² was adopted. This is an internationally accepted code of conduct for conducting research.
- ◆ In 1964, the 18th World Medical Assembly, meeting in Helsinki, Finland, adopted the Declaration of Helsinki³. It was revised by the World Medical Assembly in 1975 (Tokyo), 1983 (Venice), and 1989 (Hong Kong). The Declaration states basic principles for clinical and non-clinical research. Although these principles were developed specifically with biomedical research in mind, they stand as precedent for later legislation and are important historically.

- ◆ On July 12, 1974, the then President Nixon signed into law, the National Research Act (Public Law 93348). As a result, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created. The Commission was charged to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects, and to develop guidelines, which should be followed to assure that such research is conducted in accordance with those principles.
- ◆ In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued the Belmont Report⁴. The Tuskegee Syphilis Study⁵ was an impetus for the Belmont report.

The Code of Federal Regulations for the Protection of Human Subjects (45 CFR 46)⁶ went into effect in August, 1991. It is this legislation to which we, as Extension faculty, are responsible. This legislation holds that all institutions conducting research involving humans comply with this legislation and its provisions. Each institution may (and does) interpret this legislation individually as long as the institution holds to the provisions of the law, in this case, respect for individuals (specifically personal autonomy, confidentiality, and privacy); beneficence (specifically, doing good, minimizing harm, and ensuring the well being of the participants); and justice (specifically, the fair distribution of benefits and burdens).

INSTITUTIONAL REVIEW BOARDS

All of these events lead to establishing what universities and research facilities call the IRB or the Institutional Review Board. The IRB is a group of individuals from the university, the community, and often consumer groups who gather to review proposals from faculty or employees that will involve collecting data from individuals. Typically, this is called research and each university has its own definition of research. When an IRB reviews an application, they look to see that eight conditions are met. These conditions include:

1. an explanation of the purposes of the research;
2. description of any reasonably foreseeable risks or discomforts to the subject;
3. description of any benefits to the subject or to others which could be expected;
4. identification of appropriate alternative treatment, if any;
5. how confidentiality of records identifying the subject will be maintained;
6. if there is a potential for more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. whom to contact for answers for questions about the research, for questions about the participants rights in research, and whom to contact in the event of a research-related injury to the subject; and
8. that participation is voluntary and that the participant may refuse to participate or discontinue participation in any or all of the procedures without penalty or loss of benefits⁷.

The IRB reviews the application which details out how each of these conditions will be met. In addition, an explanation of how informed consent will be obtained (the voluntary participation condition) must be included. If the application involves special populations (like pregnant women, children, prisoners, and the mentally or physically challenged individuals), a more thorough review will be conducted (called a full board review). Most of the educational program evaluations that extension implements will meet the requirements of what is called an exempt review (the application is exempt from full board review) or expedited review (the application is reviewed by a sub committee of the full board). Exempt reviews are the least involved and the review is complete in the shortest amount of time. Expedited reviews take a little longer as the subcommittee must meet and review them. Full board reviews are the most involved as the entire IRB must meet to review and discuss the application.

IMPLICATIONS FOR FACULTY

Because each university interprets the federal legislation according to its own guidelines, the definition of research changes from institution to institution. A broad definition is activities involving human subjects from whom any information is collected which may be reported in a professional journal, at a professional meeting, to a funder, or as a report to an outside entity. When Extension faculty evaluate the outcomes of their programs, there is the potential for the findings to be reported outside the university, especially if the programs are successful in making a difference to the participants. Faculty have a responsibility to know how their university defines research and how that relates to their work and to institutional review.

However, Extension faculty also evaluate the participants reactions to the program separate from the outcomes of the program. Typically, if these data are used for programmatic improvement, it is not considered research. The catch 22 that occurs here, however, is if you collect information for programmatic improvement and find that your program is just super, or novel, or innovative and you want to tell the world, the line to research has been crossed and IRB review would be necessary. This presents an additional complication as most IRBs don't like to approve programs after the fact.

The questions at the beginning of this article were developed by Kay Rockwell at the University of Nebraska-Lincoln as a guideline for faculty for determining whether or not institutional review would be necessary. As Extension Faculty, we have the responsibility to ensure that participants of our programs are protected in the collection of evaluation data. We have the obligation to ensure that those safeguards are in place when we begin our evaluations. We have the right to insist on those protections for ourselves and our participants.

So even though you may not think you are doing "research", we have a responsibility to understand how the university interprets the federal legislation, and an obligation to help our faculty understand their responsibilities to their participants. Failure to fulfill these responsibilities and obligations leaves the participants, the faculty, and the university at risk. The IRB police are out there and watching.

