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Conducting Research with Human Subjects

When research involves people, researchers have the additional responsibility to address ethical and legal guidelines related to human subjects. This newsletter presents information and resources regarding research with human subjects, and shares some faculty and student views regarding their experiences in this area.

If planning to work with human subjects, researchers must address several issues before they begin their study, including obtaining the informed consent of participants and protecting them from potential harm due to their participation in the study. Informed consent is usually obtained through the use of a document prepared by the researcher describing the research and participant's role. This document must be reviewed and approved by the WSU Institutional Review Board (IRB) before you begin your study. Templates to assist in the preparation of an informed consent document may be found at www.irb.wsu.edu.

Because some participants may be extremely vulnerable, additional protection must be provided to them. Live human fetuses, children, prisoners, the cognitively impaired, and people with severe illnesses are among the vulnerable populations identified by the U.S. Department of Health and Human Services Office for Human Subjects Protections (see *Institutional Review Board Guidebook*, Chapter 6). WSU's IRB will review your IRB application to determine whether your research is exempt from human subjects review requirements and whether potential participants are members of one or more of the vulnerable groups described above.

Responsible research is a worthwhile goal, especially when your research involves people. Following the appropriate policies, procedures, and guidelines, planning your research carefully, working thoughtfully with your participants, and trying to conduct yourself ethically at all times will help make your research experience a successful one for you and your participants.

—Patricia Sturko, Associate Dean, Graduate School

Message from the Vice President for Research and Dean of the Graduate School



Howard Grimes

In the area of human subject research, enormous potential exists for scholarship and discovery through which to benefit society. Of course, with these benefits come the risks of a study's possible negative impact on the subjects we are trying to help. And while much behavioral research involves no physical intervention or physical risk, some investigations could present psychological harm if they involve deception and/or provide subjects with unwelcome information about themselves.

Faculty and graduate students at WSU who conduct human subject research must understand the risks as well as the benefits, and weigh them carefully. Fortunately, the Institutional Review Board (IRB) acts as a steward to help keep researchers on track and to assure that they are

always mindful of the safety of their participants. The IRB also works to establish the reliability of human subject research according to established social conventions.

As a faculty member or graduate student, when you plan to work with human subjects, it's important to educate yourself and keep current on IRB guidelines and regulations. Even one case of carelessness or misconduct can destroy the reputation of an institution and its researchers. It is imperative that researchers seriously consider how to guarantee a positive and healthy outcome for the subjects. What lies at the heart of human subject research is this: never sacrifice the safety of your participants. Such acts of scientific misconduct could be perceived as deliberate; they also undermine progress and place scientific values at risk.

Conducting any type of research is a collective experience wherein researchers exchange their knowledge and discovery with a world that expects honesty, integrity, and high ethical standards. We researchers should always work toward maintaining the highest levels of research integrity and ethical behavior, checking those against the guidelines of the IRB. We should see the IRB review process as a significant step in our course of research to protect the subjects who agree to participate in our studies.

Howard Grimes

*Vice President for Research
and Dean of the Graduate School*

Research Involving Human Participants and Institutional Review Boards (IRBs)

Introduction

Research involving human participants is essential for the advancement of scientific knowledge and understanding in many disciplines. At Washington State University there are many ongoing research projects involving human participants. In order to ensure that human participants in research are protected from harm, a system of laws and regulations has evolved to implement a formal review process for such activities. The mechanism for review is through the formation of Institutional Review Boards (IRBs).

Washington State University IRB

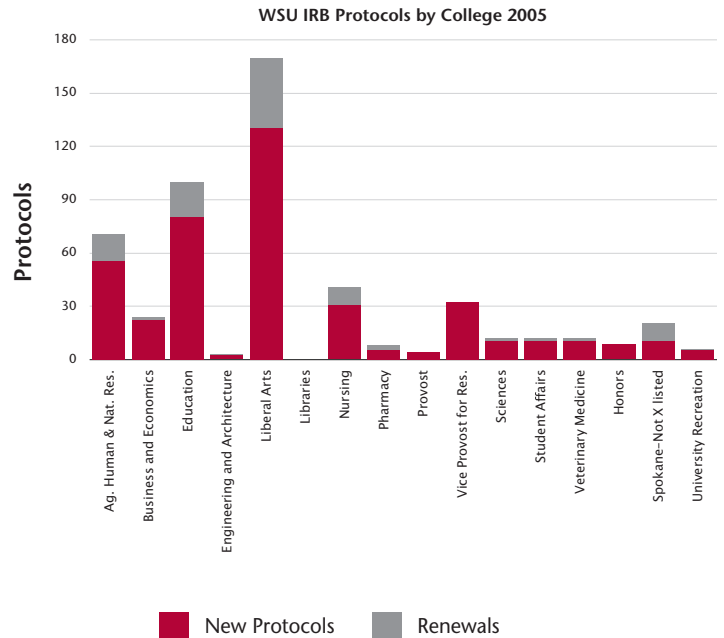
The IRB at WSU was formed in 1974. Because of changes in the regulations and evolving interpretations of the regulations by federal agencies, the IRB constantly makes adjustments and changes. The WSU IRB is a presidential committee supported by the Office of Research Assurances (www.irb.wsu.edu); it reviews all research involving human participants conducted by WSU faculty, staff, and students.

Summary of recent changes to the WSU IRB

From late 2006 through 2007 the University convened a special committee composed of faculty and senior administrators (from colleges, departments, and units that have frequent submittals to the IRB) to evaluate WSU's human participant review process. The committee worked closely with the IRB and Office of Research Assurances to present a number of suggestions designed to improve the IRB review process, then implemented and communicated the suggested changes to faculty, staff, and students. See the figure to the right for the modified human subject review process.

Effective February 1, 2008, the following changes were made:

- The IRB will only review projects that meet the definition of research.
- Principal Investigators (PIs) on IRB applications must be WSU faculty or staff.



- Forms for both exempt and non-exempt applications were modified.
- The process for the evaluation of exempt research applications has been modified.
- Initiation of Collaborative Institutional Training Initiative (CITI) for Web-based human subjects training.

Go to www.irb.wsu.edu to view modified procedures and forms.

ORA personnel are available to assist all researchers with IRB related questions. Please call Malathi Jandhyala at 509-335-3668 or Patrick Conner 509-335-7195, or visit our office Web site at www.ora.wsu.edu.

—David Clark, Director, Office of Assurances



Q&A with Professor Craig Parks

Human Subjects Research

Q: **What type of research are you most involved in?**

A: Broadly, I research interpersonal interaction, including problem solving and decision making. For example, we conduct a study wherein subjects are asked to contribute \$100 to a cause that will benefit everyone. There is no communication between subjects, so no one can gauge how much others are participating. We then ask the subjects whether they would be willing to contribute \$200 if we gave it to them. Most people look out for their own interests. They imagine everyone else will give so they don't have to. Through repeated trials we can watch the series of decisions they make.

Q: **How do you define Human Subjects Research?**

A: This is anytime a person is asked to perform a routine task, nothing physically or psychology invasive; they simply come in and perform everyday tasks. For example, in the experiment with money, you and I make these types of decisions every day. At holiday time, on the way into Shopko, we have a decision whether to give money to the Salvation Army.

Q: **Obviously, you face challenges and ethical questions when performing this type of research... What seems to challenge you the most?**

A: Sometimes in experiments I have to be mildly deceptive. For example, with the experiment I mentioned, subjects need to think they're working with other subjects in "real time" because we can't predict how people are going to react. During the debriefing, I explain to the subjects that they didn't *actually* interact with subjects in real time. Most people are fine with this. Above all, we take great care with how we treat these subjects.

Q: **What type of review process do you go through when conducting research?**

A: We have a three-tiered internal review that includes filling out a detailed set of forms. We have a checklist that our colleagues complete to let us know if there are any problems or questions, and if so, we need to know what they are so we can address them. After the colleagues complete the checklist, the forms go off to the chair

so that he or she can look them over for problems or questions. Once the forms pass through that phase, they go to the IRB for a last look. At this step in the process, the IRB can still see problems and ask the researchers to address them and resubmit the forms.

Q: **Is there a different review process for reporting results?**

A: In reporting results, we can safely assume that the research has already been approved by the IRB and flagged for ethical concerns. I believe the system works. In my work as an editor and associate editor for journals, I read about 100 papers a year. By the time researchers are attempting to publish their findings, we would hope there would be no questions about methodology. If there were serious ethical issues, I would suggest the researcher rerun the entire study.

Q: **I've heard the term "over-studied" especially in regard to the so-called vulnerable groups. What does that mean to you?**

A: One of the groups I feel has been over-studied is school children. Because so many people collect data on that particular group, the resource pool can become contaminated. It's as though these "veterans" are so used to being studied that the research isn't accurate.

Q: **What advice do you have for graduate students entering fields that involve Human Subjects Research?**

A: Educate yourself on the dos and don'ts; know the ethical issues you will confront and what others are doing in laboratories versus the field. There are unique challenges in this type of research. Ph.D.s, especially, should have a complete understanding of all the work with living organisms that has come before them.

—Interview conducted by Cindy Hollenbeck,
Communications Coordinator, Graduate School,



A Student's View

Navigating the Human Subjects Review process

Much of my work as a graduate student in sociology requires approval from the IRB before collecting my data. During the last three years, I have requested and received Human Subjects Review approval for several projects. This requires that I go out onto the streets of Pullman on Halloween and the surrounding weekends to catalog what people are wearing and ask them about their choices. At other times of the year I show college students the photos of adults in Halloween costumes and ask them to describe the costume and imagine what the person shown might have been trying to communicate with his or her choice.

My first Human Subjects Review form was difficult to interpret and I submitted it at the last minute before an important event where I needed to collect data. The Office of Grant and Research Development (OGRD) handled my request and was very helpful. The staff person who received my form taught me about the approval process and pointed out areas where an otherwise simple project that might have been processed as “Exempt,” in fact, required additional review. Now, when I ask for approval for data collection projects that require review by the full board, I aim to submit my paperwork far in advance. As a social scientist, I deeply appreciate the efforts of the OGRD staff.

Applying for Human Subjects Review approval has also encouraged me to think about the ethical implications of my research during the earliest planning stages. I have always been very concerned with the impact my research methods might have on the participants. Now I spend even more time designing my data collection projects to ensure confidentiality and anonymity for the participants. In the courses I teach, I emphasize ethics in social research and policy applications. As human subject researchers we must value the safety, comfort, and security of the people who generously share their time and thoughts with us.

—Craig Macmillan, graduate student, sociology

Conducting research and creating research activities allow us to explore the complex questions that most interest us. There are many reasons to understand and abide by the rules that guide the use of human subjects in research. The most obvious reason is to ensure the fair and safe treatment of the participants in our studies.

—Jane G. Payumo, graduate student



Conducting Ethical Research with Human Subjects

Many researchers at WSU, including faculty, staff, and students, conduct research on human subjects. It is critical that we conduct our research ethically and with sensitivity to protect the rights and dignity of those subjects. WSU requires that all researchers comply with the processes designed to guarantee these protections and does this through the work of its Institutional Review Board (IRB). Although these processes have changed recently, the emphasis on protecting the rights of human subjects remains at the forefront.

Brief history

In the past, humans were sometimes studied without respect for individual dignity or safety. Many of us remember the horrific research done on the Tuskegee airmen. And, of course, the Nazi concentration camp stories where people were deliberately tortured and killed show us the immensely negative consequences of unethical research. Even in the social sciences research we conduct today, people may be asked to disclose personal, possibly embarrassing, information; and they must be guaranteed the right to privacy and dignity. The IRB Resources Web page, www.irb.wsu.edu/resources.asp, is a good source of information on past practices and current ethical guidelines.

My experiences

My research focuses mainly on the teacher induction process, particularly in rural and small schools. I often perform surveys and interviews with teachers and school district administrators and need to gather assent forms from them prior to their participation. And since I publish in national professional journals, I seek permission from the IRB before I begin my research.

In the College of Education programs, we have many students pursuing master's degrees who complete a final project, usually involving research in the K-12 school setting. If they're working with subjects under 18 years old, they need to get parental consent

as well as the students' assent. Many projects involve working with students for whom English is not their first language and so the communication with parents and students also needs to be translated into the language(s) spoken at home. Since these projects are seldom published at the national level, and usually involve typical classroom practices, the researchers are not required to get IRB approval, and instead follow processes developed by the College of Education.

Human subjects study at WSU

The best place to start is with the IRB Web site, www.irb.wsu.edu, which has links to pages that explain the processes and offer forms. Recommendations for projects that do not require IRB approval are available at www.irb.wsu.edu/class_projects.asp. For a full explanation of current procedures, you should visit the IRB forms page at www.irb.wsu.edu/forms.asp. Regardless of whether or not the study requires IRB review, it is important that the basic tenets of ethical research are followed, including maintaining confidentiality, gathering consent and assent forms, and allowing subjects to withdraw from the study at any time without fear of retaliation. In addition, all researchers at WSU are required to take online research training offered by the Collaborative Institutional Training Initiative (CITI): www.irb.wsu.edu/CITI.asp.

Concluding thoughts

All researchers who conduct studies with human subjects have the responsibility to follow ethical research guidelines, even if the federal government doesn't require them to do so. It is up to all of us to maintain high standards in order to protect those who participate in our studies. WSU IRB professionals are very knowledgeable and helpful, and are the best source of information about conducting ethical research.

—June Canty, Ed. D., Professor and Director
College of Education programs



Resources

- IRB Guidebook: http://www.hhs.gov/ohrp/irb/irb_guidebook.htm
- The Belmont Report: www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm
- Federal Regulations: <http://www.spoaccess.gov/cfr/index.html>
- WSU Human Subjects: president.wsu.edu/office/presidential-committees/human-subjects.html
- www.irb.wsu.edu/
- Office of Research Assurances: www.ora.wsu.edu/
- Office for Human Research Protections: www.hhs.gov/ohrp/
- IRB resources: www.irb.wsu.edu/resources.asp
- Recommendations for Class Projects: www.irb.wsu.edu/class_projects.asp
- Human Subject Forms and Templates: www.irb.wsu.edu/forms.asp
- Required Human Subjects Training: www.irb.wsu.edu/CITI.asp.
- Guidelines: ohsr.od.nih.gov/guidelines/GrayBooklet82404.pdf

Tips

for conducting research with human subjects

- Before you conduct an interview, explain to the participant what it will be about and how long it will take. Include this information in your informed consent form.
- Be aware of the impact your research has on the lives of your participants.
- Treat participants respectfully at all times, and be particularly sensitive to their needs if they are members of a vulnerable group, such as children or prisoners.
- Ensure participant privacy. Design your study so that participants can choose to reveal information to you in a confidential manner.
- Protect participant identities so that the data collected will not harm them in any way.
- When you ask permission to conduct a study, be sure that all parties are aware of the nature and extent of the study and what it involves.

Last Words

“There are unique challenges in human subject research. Educate yourself about the rights and wrongs and the dos and don’ts. Study what other researchers are doing in the field and in the lab. Know the ethical issues you will confront. Gain a complete understanding of the research performed on living organisms that has come before you. Always respect your volunteers who are participating in an effort to further education.”

— *Craig Parks, professor of psychology*