

BUCK-I·RB NEWS

NEWSLETTER ABOUT THE INSTITUTIONAL REVIEW BOARDS AT OSU

**SPRING 2006
VOLUME 1 ISSUE 2
CONTENTS**

Revised IRB Application Applications for IRB review medical and non-medical research	1
Community IRB Member retires after 19+ years of dedicated service ORRP recognizes retiring prisoner representative	1
All About ORRP – The Office of Responsible Research Practices Overview of ORRP	2
IRB Training for Graduate Students Workshops offered each quarter	2
IRB Basics Excerpt from journal article by Biomedical IRB Vice- Chair	2
The Top 3 Things to Remember in Social, Behavioral, and Educational Research How to keep research on track	4
Watch for in the Next Buck I·RB News... Upcoming topics	4

Revised IRB Applications

The revised IRB application for initial review is available online at <http://www.orrp.ohio-state.edu/humansubjects/irb/intialreview.cfm>. This application is comprised of a standard set of questions for all investigators, with supplemental appendices for specific types of research. Investigators should download an application before each use to ensure that they have the most current version. New applications for review of exempt research and for continuing review of non-exempt research will be available soon.

Community IRB Member retires after 19+ years of dedicated service

Charles A. Dozer served on the Biomedical Sciences Institutional Review Board for over 19 years. Charles is a retired correctional officer who served as the prisoner representative, as well as a non-scientist and non-affiliated member of the IRB.

According to federal regulations, IRBs must have at least one member of the IRB who is either a prisoner or a prisoner representative with appropriate background and experience to review research involving prisoners. Prisoners are entitled to special protections in research (45 CFR 46 Subpart C) due to their limited autonomy. IRBs must also have both non-scientist and non-affiliate members by regulation.

In 19 years, Charles rarely missed an IRB meeting and brought a welcomed perspective to the review process. He will truly be missed.

All About ORRP – The Office of Responsible Research Practices

The mission of the Office of Responsible Research Practices (ORRP) is to support the University's goal of promoting the ethical conduct of research involving human and animal subjects.

ORRP staff support the following review boards:

- ❖ IRBs –
 - ❖ Behavioral & Social Sciences
 - ❖ Biomedical Sciences
 - ❖ Cancer
- ❖ Institutional Biosafety Committee (IBC)
- ❖ Institutional Animal Care and Use Committee (IACUC)
- ❖ Privacy Board for Exempt Human Subjects Research

ORRP also provides faculty, staff, and student education on the Responsible Conduct of Research, pre-review of protocol submissions for compliance with regulatory requirements, and implementation of the University's Conflict of Interest Policy.

A listing of our staff and their contact information can be found on the ORRP website at <http://www.orrp.ohio-state.edu/staff.cfm>.

IRB Training for Graduate Students

The Office of Responsible Research Practices and the Graduate School jointly hold educational workshops on human subjects protection for graduate students. These workshops provide a brief overview of human subjects research regulations and ethics, as well as practical tips for submitting to the IRB. Workshops are held each quarter. Announcements for upcoming sessions can be found on the ORRP website and are sent to those who register online for email notifications. To learn more, visit our website at www.orrp.osu.edu.

IRB Basics

(Excerpted from Miser WF. Educational Research—To IRB or Not to IRB? *Fam Med* 2005; 37(3): 168-73)

Federal regulations require that all research involving human subjects is reviewed and approved by an IRB prior to conducting the research. The major purpose of the IRB is to protect the rights and welfare of the participants involved in the research.

Each institution that accepts federal funding for research

is mandated to have at least one IRB. By regulation, each IRB should consist of at least five members, both men and women, from varied professions. In addition to members who have expertise in science, the IRB should also have at least one member whose primary concerns are in nonscientific areas, and one member who is not otherwise affiliated with the institution. The number and size of the IRB varies by institution. For example, The Ohio State University has four IRBs that review human subjects research – Behavioral and Social Sciences, Biomedical Sciences, Cancer, and Industry-Sponsored, the latter of which is outsourced to Western IRB. Each IRB varies in size depending on the number of research protocols to be reviewed; the Biomedical Sciences IRB consists of nearly 30 members and alternates who meet for three to four hours every two weeks.

The IRB has authority to approve, disapprove, or require modifications to research, and must conduct continuing reviews of the research on at least an annual basis. The IRB must also verify and approve any modifications to ongoing research, may observe the consent process and research procedures, and has authority to suspend or terminate approval for research. As long as federal regulations are met, each IRB may vary how it meets

those standards, and may actually add additional procedures to meet local needs. Since IRBs vary by institution, it is essential that investigators understand the policies and procedures of their local IRB.

The research application submitted to the IRB will also vary by institution, but at a minimum must contain the information contained in Table 3. The basic criteria needed for IRB approval of human subjects research is found in Table 4.

Table 3. Minimum Information for Human Subjects Research Application.*

1. A complete description of the proposed research.
2. An analysis comparing potential risks and anticipated benefits, with assurance that risks are minimized and are reasonable in relation to the potential benefits.
3. The process and documentation of informed consent and of assent (for children or adults unable to consent for themselves).
4. An equitable selection of participants in terms of gender, race and ethnicity, and a fair distribution of benefits among the community's population.
5. Safeguards that protect vulnerable populations

- that may be susceptible to pressure to participate (e.g., children, prisoners, or other vulnerable populations).
6. Safeguards that ensure that recruitment does not invade the individuals' privacy and confidentiality of information provided during the research.
7. A plan for collecting, storing, and analyzing data in a secured manner.
8. Scientifically valid research design and methods that justify participants being exposed to the anticipated risks.

Table 4. Basic Criteria for IRB Approval of Human Subjects Research.*

1. Risks to participants are minimized:
 - a. By using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and
 - b. Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and

- to the advancement of knowledge.
3. Selection of participants is equitable.
4. Informed consent will be sought from each prospective participant or his/her legally authorized representative.
5. Informed consent will be appropriately documented.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
7. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
8. When some or all of the participants are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect participants.

* Adapted from 45 CFR Part 46.111.⁵

The Top 3 Things to Remember in Social, Behavioral, and Educational Research

1. *Do not enroll more participants than stated in the protocol or IRB application without prior IRB approval.*

The number of participants to be studied in the research must be stated in the original protocol and should be based on sound research methods. When approving research, the IRB must consider the number of participants who will be exposed to the research interventions to evaluate the risks and benefits of the study. If it appears that the number of participants will need to be increased to meet the scholarly goals of the research, investigators must submit and receive IRB approval for an amendment before proceeding.

2. *Do not change survey or interview questions without IRB approval.*

By regulation, changes may not be made to approved research without prospective IRB review, except when necessary to eliminate apparent immediate hazards to participants (rare).

Proposed changes must be submitted to the IRB via an Amendment Request form (available on the ORRP website). Investigators will receive written confirmation of IRB approval of amendments and should not enact changes until then.

3. *Do not begin recruitment or data collection without IRB approval.*

Investigators may not begin research, including recruitment of participants or data collection, without first receiving written notice of approval from the IRB. When modifications are required following IRB review, investigators must forward their responses to ORRP for expedited IRB review. Once modifications have been accepted, the PI will receive an IRB approval letter. When the letter is received, the research is approved and may begin.

In the Next Buck I·RB News...

- Using the PI Profile
- AAHRPP Accreditation
- The IRB Policy Committee
- Recent Revisions (ORRP website, forms, etc.)

The Ohio State University Office of Responsible Research Practices

1960 Kenny Road, Columbus, Ohio
43210
Phone: 614-688-8457 Fax: 614-688-0366
www.orrp.osu.edu

BUCK-I·RB NEWS is published quarterly for investigators, research staff, and IRB members at The Ohio State University.

TANI COLVIN, MA, CIP
Education Administrator/
Newsletter Editor
colvin.51@osu.edu

JUDY NEIDIG, PhD
Director
neidig.1@osu.edu

KAREN HALE, RPh, MPH, CIP
Education Specialist
[hale.5@osu.edu](mailto: hale.5@osu.edu)