

BUCK-I·RB NEWS

NEWSLETTER ABOUT THE INSTITUTIONAL REVIEW BOARDS AT OSU

SEPTEMBER 2006 Contents

Revised IRB Forms

Various IRB submission and reporting forms are changing 1

ORRP Website Gets New Look

Website redesigned for easier navigating 2

New Committee Formed

IRB Policy Committee established to develop IRB policies 2

Workshops

Upcoming ORRP educational offerings 2

Non-Scientist IRB Members Invaluable

Special thanks to these IRB members 2

Did You Know...?

Brief but important information 2

REVISED IRB FORMS

To improve information exchange between investigators and the IRBs, the Office of Responsible Research Practices will soon post several revised application and reporting forms for review of initial and ongoing research.

The following forms have been updated:

Application for Initial Review

Questions regarding proposed participant numbers and study populations have been changed in an effort to prevent apparent discrepancies at continuing review. Informed consent and risk questions have been revised to remove redundancies. Additional guidance has been added throughout, and improvements have also been made to numerous appendices (e.g., data repositories).

Continuing Review Application

Formatting and questions were changed throughout to match the initial application (e.g., study population). Numerous revisions were made and questions combined to remove redundancies. Appendices were added to make it easier for investigators to request expedited continuing review, changes in study personnel or participant numbers, and to

report unanticipated problems.

Final Study Report

(formerly, Termination Report) Nine questions have been deleted, and others combined or revised, to assist investigators in efficiently providing the IRB with an overall summary of the approved research.

Event Reporting Form

The adverse event reporting form has been replaced with a new form for prompt reporting of adverse events, unanticipated problems, and other information that may involve unexpected risk to research participants or others. The Event Reporting form can be used to report events occurring in either medical or non-medical research. The corresponding new Event Reporting policy is posted at <http://orrrp.osu.edu/humansubjects/osupolicies.cfm>.

These new forms will be available on the ORRP website on or before October 1, 2006 at <http://orrrp.osu.edu/humansubjects/forms.cfm>. Former versions of the forms will continue to be accepted for review until January 1, 2007.

ORRP Website Gets New Look

Please take a moment to look at our newly designed website at www.orrp.osu.edu. All Departments in the Office of Research will use this new layout.

Because of the wide variety of administrative support services offered by ORRP, the home page provides links to four major research-related areas:

- Animal Care and Use,
- Biosafety,
- Conflict of Interest, and
- Human Subjects.

Forms, news, frequently asked questions, and links to other resources are also available on the site. Please sign up for email updates and continue to visit the ORRP website for new information.

New Committee Formed

The IRB Policy Committee (IPC) was established to develop, review, and approve policies and procedures for the University's human research protection program.

The IPC is appointed by the Senior Vice President for Research and is comprised by the Chairs and Vice-Chairs of the IRBs, ORRP staff, and representatives from the Office of Research, Research Foundation, and the faculty.

As new policies are approved by the IRB Policy Committee, they are posted on the ORRP website at <http://orrp.osu.edu/humansubjects/osupolicies.cfm>. Recent postings include the following new or revised policies:

Research Involving Human Subjects, Exempt Research, and Noncompliance.

The IPC is also charged with receiving input on ways to optimize IRB and ORRP operations, developing strategies for recruiting and retaining IRB members, and considering new initiatives for the human subjects protection program.

Workshops

Event Reporting

Investigators, students and research staff are encouraged to attend a help session on the new Event Reporting form and policy from 12-1pm on September 13th in 165 HLRI or September 18th in H1213 Ross Heart Hospital. The new form and policy replace the current process for prompt reporting to the IRB of adverse events and unanticipated problems. A session specifically targeted for SBS investigators and students will be offered fall quarter.

IRB Training for Students

OSU students are encouraged to attend an information session to learn about human subjects research. Training includes the types of studies that have these requirements, procedures and timelines for seeking approvals, and an opportunity to ask questions about specific projects. Sessions are held quarterly. Fall dates are September 28th and October 12th from 9-10am in 14 University Hall. Please pre-register for the event at <http://www.gradsch.osu.edu/>.

For more information on educational sessions, contact Tani Colvin at 292-0214 or colvin.51@osu.edu.

Non-Scientist IRB Members Invaluable

According to federal regulations, an IRB must have "at least one member whose primary concerns are in nonscientific areas." These individuals are asked to reflect community attitudes and often also represent vulnerable or underserved populations that may participate in research. A non-scientist must be present at each meeting for an IRB to vote on or approve research.

Special thanks are extended to the dedicated non-scientist members of the Behavioral, Biomedical, and Cancer IRBs for volunteering their time to the human subjects protection program at OSU.

Did You Know...?

Non-exempt human subjects research should receive continuing IRB review as long as activities involving human subjects (including data analysis with individually identifiable or coded private information) are ongoing.

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 three times a year for investigators, research staff, and IRB members at The Ohio State University.

KAREN HALE, RPh, MPH, CIP

Education Specialist
[hale.5@osu.edu](mailto: hale.5@osu.edu)

JUDY NEIDIG, PhD

Director
[neidig.1@osu.edu](mailto: neidig.1@osu.edu)

TANI COLVIN, MA, CIP

Education Administrator/Editor
[colvin.51@osu.edu](mailto: colvin.51@osu.edu)