

BUCK-I·RB NEWS

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Newsletter for Investigators, Research Staff, and IRB Members

Welcome to the first edition of *Buck-I·RB News*. This newsletter was developed by The Ohio State University Office of Responsible Research Practices (ORRP) to communicate information, regulatory updates, and answers to frequently asked questions relating to human subjects research to OSU investigators, research staff, and IRB members. *Buck-I·RB News* will be distributed electronically three times each year and posted on the ORRP website at <http://www.orrp.ohio-state.edu/>.

In addition to presentation of issues relevant to human subjects' participation in biomedical and behavioral research, *Buck-I·RB News* will also periodically feature "guest" articles from investigators and IRB members.

Please send comments, questions, or suggestions for future issues to Tani Colvin, Education Coordinator, at colvin.51@osu.edu. To be added

to the distribution list for *Buck-I·RB News*, sign up on the ORRP website under "Get notifications via e-mail".

Human Subjects Education Requirements

All OSU Investigators and key research personnel (individuals who contribute in a substantive way to the scientific development or execution of the project) who participate in human subjects research must be trained in human subjects protection. The University has selected the Collaborative IRB Training Initiative (CITI) web-based course with core education modules to satisfy this requirement.

Initial training must be completed before DECEMBER 1, 2004 for all new research submissions and prior to requesting continuing IRB

review for ongoing research after this date.

The modules are divided into two tracks: Biomedical Research and Social and Behavioral Research. Investigators who conduct both types of studies should take the track that is more closely related to their research. Each module will take from 10 to 30 minutes to complete and contains a quiz that must be passed with a minimum score of 80%.

To meet OSU requirements, investigators must complete the CITI Basic Course in Biomedical or Social and Behavioral Research in addition to any other human subjects training (e.g., NIH).

Continuing human subjects protection education (specific requirements and format not yet determined) will be required for all OSU investigators and key research personnel every three years following completion of the initial training.

To access the CITI Course in the Protection of Human Research Subjects, visit the site at:
www.citiprogram.org/

For questions contact Tani Colvin, Education Coordinator, at colvin.51@osu.edu.

To read the special message from Robert McGrath, Senior Vice President for Research, regarding the human subjects protection education program, visit the ORRP website at www.orrp.ohio-state.edu.

Responsible Conduct of Research Education

All trainees supported by National Institutes of Health (NIH) Institutional National Research Service Award (NRSA) Research Training Grants (T32, T34) must receive instruction in the **Responsible Conduct of Research (RCR)**. Trainees and others seeking RCR education may use this web-based program to fulfill these requirements.

The topic areas presented in the program include the core instructional areas recommended in the Public Health Service policy on Instruction in the Responsible Conduct of Research. The following topics are discussed:

Data Management
Human Subjects
Animal Subjects
Conflicts of Interest and

Commitment
Publication
Authorship
Peer Review
Collaboration
Mentoring
Research Misconduct
Whistle-blowing

The program contains copyrighted materials made available to The Ohio State University through the RCR Education Consortium. A local content expert is listed at the end of each section for further discussion or questions regarding the topics.

An OSU username and password (Kerberos ID) are required to register for the program. Learners may exit and re-enter the program as often as they like and can review the topics in any order. There are no quizzes. Course progress is tracked (with a ✓) in the navigation links in the left sidebar.

After completing the program, the Certificate of Completion should be printed and a copy retained for documentation.

For questions or assistance, contact Tani Colvin, Education Coordinator, at colvin.51@osu.edu.

To access the Course in the Responsible Conduct of Research, visit the site at:

<https://rf.osu.edu/secure/Education/RCR/>

For more information on the NIH NSRA training requirements, see <http://grants.nih.gov/grants/guide/notice-files/not92-236.html>

For more information on the PHS policy, see <http://ori.dhhs.gov/html/programs/finalpolicy.asp>

Human Subjects Research FAQs

Because The Ohio State University receives funds from the U.S. government to support research, the institution must comply with federal regulations governing the conduct of human subjects research. Institutional Review Board (IRB) review of human subjects research is required to protect the rights and welfare of participants in research conducted under the auspices of the institution(s) with which the IRB is affiliated.

The IRB has the authority to approve, require modifications in, or disapprove all research activities as defined by federal regulations (Department of Health and Human Services and

the Food and Drug Administration) and local institutional policy. This requirement applies regardless of the source of funding supporting the research.

The first two questions investigators and IRBs must answer are whether a proposed activity involves “research” and, if so, whether the research involves “human subjects”.

How do I know if my proposed activity involves research?

Department of Health and Human Services (DHHS) regulations define “research” as ***a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.*** For example, if the *intent* of the activity is to share knowledge by publishing or presenting the results, the activity should usually be considered research. Research is typically described in a formal proposal or protocol that includes an objective(s) and a set of procedures designed to reach that objective (i.e., systematic). In contrast, “treatment” or “professional practice” involves performing interventions designed solely to

enhance the well being of a particular individual. Food and Drug Administration (FDA) regulations define “clinical investigations” rather than research. Clinical investigation means ***any experiment that involves a test article and one or more human subjects.*** (A *test article* means any drug, biological product, medical device, food or color additive, electronic product, or any other article regulated by FDA.) The terms research, clinical research, clinical study, study, and clinical investigation are generally used interchangeably.

Because investigators at the University receive funds from both Agencies (DHHS and FDA) to support research, the institution must comply with both DHHS and FDA regulations governing the conduct of human subjects research.

How do I know if my proposed activity involves human subjects?

Federal regulations define “human subjects” as ***living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the***

individual or (2) identifiable private information.

For oversight purposes, the University has generally interpreted this definition to include all data and biological materials obtained from persons living or dead. Therefore, your research probably involves human subjects if it includes:

- Performing biomedical studies on humans or on human specimens
- Administering surveys; interviewing or observing individuals
- Audiotaping or videotaping people
- Using stored specimens collected from humans
- Reviewing existing data containing identifiable private information

When am I required to seek IRB approval or exemption?

Whenever a proposed activity can be defined as research involving human subjects, IRB approval or exemption is required *before beginning the activity*. Failure to follow the University's policies, procedures, and ethical principles governing the use of human subjects in research may potentially harm the volunteers who participate in research, jeopardize the reputation of the University and its researchers, lead to disciplinary action against the

person(s) conducting the research, or result in sanctions that may prohibit all University investigators from performing research involving human subjects.

Examples of activities that may not be considered research involving human subjects include traditional classroom projects, program evaluations, or other "quality" reviews when neither the reason for the activity nor the distribution of results meets the regulatory definition of research (i.e., to contribute to generalizable knowledge). Use of existing permanently de-identified data sets or commercially available specimens are also not generally considered to constitute human subjects research because these activities do not involve human subjects as defined by the regulations.

When is human subjects research exempt?

The University has established a review process for determining that research involving human subjects is exempt from the federal requirements for IRB review. ***Investigators may not make their own determinations of exemption.*** The University's Office of Responsible Research Practices

(ORRP) is responsible for this process, as well as for providing administrative support to the University IRBs and investigators and for maintaining official institutional records regarding human subjects (and other) research. The application(s) for requesting IRB exemption can be found at <http://www.orrp.ohio-state.edu/forms.cfm?form=human>.

Examples of human subjects research that may be exempt include anonymous surveys, (non-sensitive) interviews, or observations of public behavior, and study of existing data, records, or specimens, when the information is recorded by the investigator so that subjects cannot be identified, directly or through identifiers linked to the subjects. Research involving prisoners, fetuses, pregnant women, or human in vitro fertilization is not exempt. Surveys or interviews involving children are also not exempt. Neither is prospective examination of records or specimens, or use of coded (or linked) data or specimens; this type of human subjects research requires IRB review.

Are there other requirements for conducting human subjects research?

In addition to the federal regulations requiring IRB review (or exemption) for human subjects research, the University must also comply with other federal regulations, state law, and applicable guidance involving research. Various oversight processes have been established to assure this compliance. Examples include Institutional Biosafety Committee review of research with recombinant DNA, HIPAA Privacy Rule requirements for research involving identifiable protected health information (or PHI), and the conflict of interest screening/disclosure process for all investigators conducting research.

For more information about the requirements for performing human subjects research or for contacts, forms, or other assistance contact ORRP at 614-688-8457 or visit the Office of Responsible Research Practices website at: <http://www.orrp.ohio-state.edu>.

OSU's New Federal Wide Assurance (FWA)

Each organization conducting human subjects research must have an assurance filed with the federal Office for Human Research Protections (OHRP). As

part of this Federal Wide Assurance (FWA), OSU asserts that human subjects research follows federal guidelines. By signing this document, the institutional official has documented the University's commitment that:

- All non-exempt human subjects research will be reviewed and approved by the IRB before it is undertaken;
- Legally effective informed consent or a consent waiver will be obtained for all human subjects research;
- Written procedures for human subjects protections will be followed;
- Serious non-compliance with human subjects requirements will be reported to OHRP;
- Sufficient IRB resources will be provided;
- IRB members, researchers, and research support staff will receive human subjects training;
- Human subjects research will be limited to locations for which the University has authority and oversight responsibility.

A copy of the University's Federal Wide Assurance (FWA # 00006378) is posted at <http://www.orrp.ohio-state.edu/FWA.cfm>. The Assurance is valid through January 28, 2007.

Research Performance Sites

An OSU IRB may only approve human subjects research activities at locations for which the Board has an understanding of the local research context and the University has oversight mechanisms in place. IRB approval of research is limited to the performance sites approved by the University and listed at <http://www.orrp.ohio-state.edu/documents/ResearchPerformanceSites.doc>.

Under the University's Federal Wide Assurance, OSU employees, staff, and students may not "engage" in research activities at sites that are not on the list of approved OSU research performance sites. Persons are considered to be engaged in human subjects research when they:

- 1) Intervene or interact with living individuals for research purposes;
- 2) Obtain individually identifiable private information for research purposes; or
- 3) Receive a direct federal grant to support human subjects research.

Since OSU is automatically engaged in human subjects research whenever it receives a direct federal grant, an OSU IRB must review and approve

research whenever an OSU faculty member receives federal funds. This is required even if there will be no research performed at any Ohio State site.

Limited use of non-OSU facilities (e.g. schools, nursing homes, businesses, etc.) may be permitted for some research activities. However, the facility or the facility's personnel at the non-OSU site must not engage in the research.

When more than limited use of outside facilities or involvement of individuals who are not OSU employees or students that would engage them in research activities is proposed, IRB approval by the external institution's IRB or redesign of the project will be required to perform the research.

Additional guidance on this topic is available from OHRP at: <http://www.hhs.gov/ohrp/human-subjects/assurance/engage.htm>.

Institutional Review Board Actions

According to federal regulations, the IRB has the authority to approve, require modifications in, or disapprove research activities involving human subjects. An IRB may also defer making a decision on proposed research submitted for review. These four actions – **Approval**, **Modifications Required**, **Deferral**, and **Disapproval** are further explained below.

Approval: *The IRB has determined that the regulatory criteria for IRB approval of the research have been met.* When research is approved by the IRB, the principal investigator receives a letter indicating the period of approval specified by the Board (up to 365 days). The approval letter also informs the investigator of responsibilities for study oversight; reporting serious, unexpected adverse events and unanticipated problems; seeking IRB approval before initiating study changes; and for requesting IRB re-approval for continuing research. Research that has been approved by the IRB may be subject to further review by the Vice President for Research (VP).

Modifications Required: *The IRB is able to specify explicit revisions to the research, requiring simple concurrence by the investigator, that are needed to satisfy the criteria for approval.* When modifications are required, the principal investigator receives a letter specifying the modifications to the research that were required by the Board. The Chair designates an IRB member (usually the primary reviewer) who will subsequently review the investigator's responses using expedited procedures outside the convened meeting. The reviewer may approve the revised research on behalf of the convened IRB, but may not disapprove the research. Research revisions that cannot be approved by expedited review will be returned to the convened IRB for re-review. Research may not begin until the IRB verifies that the required modifications have been made.

Deferral: *Additional information, which may include substantive changes to the research proposal, consent form(s), application, or other materials, is required before the Board can make a determination.* When research is deferred, the principal investigator receives a letter specifying the Board's reasons for deferral. One or

more members of the IRB may be appointed to discuss the deferral with the investigator. The revised application will be scheduled for re-review at a convened meeting of the IRB. The IRB may request that the investigator attend the convened meeting at which the revised application will be reviewed. The research may be subsequently approved, disapproved, (re)deferred, or the Board may require modifications. Note: OHRP guidance specifies that an IRB may not approve research contingent upon substantive modifications or clarifications.

Disapproval: *The risks of the proposed research procedures outweigh any potential benefit to be gained.* When research is disapproved, the principal investigator receives a letter outlining the Board's reasons for disapproval. The investigator will be given an opportunity to respond in person or in writing. No research may be initiated. The Board's vote is final; neither the Vice President for Research or any other office or official of the institution may approve a research activity that the IRB has disapproved.

The Ohio State Institutional Review Boards

The University has three internal IRBs for review of behavioral, biomedical and cancer research. The University also contracts with Western Institutional Review Board (WIRB) to review and monitor industry-sponsored clinical trials. The 2004-2005 OSU Boards and current leadership are listed below.

Behavioral & Social Sciences

Chair, Thomas Nygren
Associate Professor, Psychology

Vice-Chair, Jeanne Clement
Associate Professor, Nursing

Biomedical Sciences

Chair, Karla Zadnik
Professor, Optometry

Vice-Chair, Fred Miser
Associate Professor
Family Medicine

Cancer

Chair, William Carson
Professor, Surgical Oncology

Vice-Chair, Thomas Raasch
Associate Professor, Optometry

The Ohio State University Office of Responsible Research Practices

1960 Kenny Road, Columbus, Ohio 43210
Phone: 614-688-8457 Fax: 614-688-0366
<http://www.orrp.ohio-state.edu/>

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KAREN HALE, RPh, MPH
Education Specialist/Newsletter Editor
<mailto:hale.5@osu.edu>

JUDY NEIDIG, PhD
Director
<mailto:neidig.1@osu.edu>

TANI COLVIN
Education Coordinator/Editorial Assistant
colvin.51@osu.edu