

BUCK-I·RB NEWS

NEWSLETTER ABOUT THE INSTITUTIONAL REVIEW BOARD AT OSU

JUNE 2007 Contents

CITI Courses in Human Subjects Protection

Information about OSU training requirements and the web-based courses

1

Optional CITI Courses

Good Clinical Practices, HIPAA, International, Research and RCR courses now available

1

Secondary Subjects

Determining whether family members are research subjects in pedigree and survey studies (excerpted from JAMA)

2

Understanding IRB Review Processes

Some differences between exempt, expedited, and convened reviews

3

Did You Know...?

Brief but important information

3

COLLABORATIVE IRB TRAINING INITIATIVE (CITI) HUMAN SUBJECTS BASIC AND REFRESHER COURSES

All OSU Investigators and key research personnel who participate in human subjects research, IRB members, and IRB staff must be trained in human subjects protection. The University has selected the Collaborative IRB Training Initiative (CITI) web-based course to meet this requirement. Initial and continuing education are required as explained below.

The **CITI Basic Course** provides initial training. Discipline-specific modules are available for Biomedical and Social and Behavioral research. Successful completion of the Basic Course satisfies the training requirement for 3 years.

Continuing education in human subjects protection is obtained by taking the **CITI Refresher Course**. These modules offer a brief review of the basic course content. There are two educational tracks for the Refresher Course: Biomedical and Social and Behavioral. Successful completion of these modules will satisfy the training requirement for an additional 3 years. **Note: taking the Refresher Course will not satisfy the initial training requirement.**

As a reminder, an email will be sent to each individual who has not completed the Refresher Course within 60 days of the

required renewal date. To check completion dates for a CITI course, log on to the CITI website at www.citiprogram.org and click on "View Course Completion History," or use the PI Profile in the OSU PI Portal, which can be accessed under "Tools" at <http://rf.osu.edu/>.

Training for all individuals participating on a project must be current for IRB submissions (initial or continuing review) to be processed.

To access the CITI Courses in the Protection of Human Research Subjects, visit the site at www.citiprogram.org. For more information on training requirements or for step-by-step instructions on accessing the courses see the ORRP website at <http://orrrp.osu.edu/humansubjects/citi.cfm>.

For questions, contact Tani Prestage, Education Administrator, at prestage.2@osu.edu.

Optional CITI Training Courses

New optional courses that can be used to supplement required training are now available to OSU faculty, staff,

and students from the Collaborative IRB Training Initiative.

Free courses are offered in Good Clinical Practice and ICH (GCP), Health Information Privacy and Security (HIPAA), International Research, and Responsible Conduct of Research (RCR). All courses can be accessed on the CITI program site at www.citiprogram.org.

Trainees funded by NIH research training grants can use the CITI RCR course to meet NIH training requirements. A one-day OSU didactic workshop is also offered every winter quarter to assist trainees in meeting these requirements. Anyone interested in RCR training may take the CITI RCR course or attend the workshop.

The CITI Basic Course in human subjects protection is a prerequisite for taking the GCP course. The course content includes GCP and ICH requirements, investigator responsibilities in drug and device studies, and safety monitoring. Up to 4 continuing medical education credits are available through the University of Miami for completing the GCP course.

The International Research course is open to the public for individuals with or without OSU affiliation. Some content is available in Simplified Chinese, French, Portuguese, and Spanish.

Further information and step-by-step instructions on accessing these courses is available on the ORRP website at <http://orrrp.osu.edu/humansubjects/citi.cfm>.

.....

Secondary Subjects

(The following is excerpted from JAMA, Protecting the Privacy of Family Members in Survey and Pedigree Research, Botkin, J.R., Volume 285(2), January 10, 2001, 207-211).

An investigator performing survey or pedigree research must determine when family members (about whom primary research participants may be questioned) are also considered human research subjects. The federal definition of a "human subject" is used to decide when family member(s) are research participants.

According to DHHS regulations, a human subject is a living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information.

Deceased persons are not human subjects according to this definition. Data collected that is "public knowledge" (versus private information) is also not protected under human subjects regulations. Examples of public information include age, body build, marital status, race, and occupation. Alternatively, "private" information is that which is generally shared only in close personal relationships between individuals.

If the identity of the primary participant in survey research is not collected – i.e., "anonymous" - and the participant does not disclose unique identifiers of family members, then these relatives are not considered subjects in the study. Family members are also not considered human

subjects if their data can be permanently "de-identified" before use. If neither is the case, to determine if family members are human subjects, an investigator must consider whether a relative can be readily identified based on knowing the subject's identity and relationship to the family member.

Family members of primary research participants are "readily identifiable" when those surveyed provide investigators with names or other unique identifiers of their family members. In general, family members are not readily identifiable when a primary subject provides the health or personal information of a family member who is identified only by his/her relationship to the subject.

When private information is obtained about relatives who can be individually identified, they are research participants or "secondary subjects." Investigators conducting survey or pedigree research must also determine if these subjects' informed consent may be necessary.

Informed consent must be obtained from secondary research subjects unless the following regulatory criteria for waiver are met:

- 1. The research involves no more than minimal risk.** (Risk is minimized when information obtained about family members is not extremely sensitive or personal and stringent data security measures will be used.)
- 2. The waiver will not adversely affect the rights and welfare of the subjects.**

3. **The research could not practicably be carried out without the waiver.**
(Inconvenience or expense as reasons will not satisfy this criterion.)
4. **When appropriate, subjects will be provided with additional pertinent information after participation.**

(Note: the research must not be subject to FDA regulations to waive informed consent.)

Investigators conducting survey or pedigree research in which primary subjects provide information about family members should first determine if these relatives are also human subjects. If so, then their informed consent to participate may be required.

Understanding the Review Processes

It is important to understand the various review processes when submitting a study for IRB review. The types of review are exempt, expedited, and convened (full).

Exempt research must fit into categories specified by federal regulation. Common examples of exempt research are surveys not linked to identities of subjects and study of existing data (records, specimens) that do not have links or codes to identifiable information. If prisoners or deception are involved, the research is not exempt. Investigators who believe their research is exempt should complete the exempt application and submit

it along with a research proposal and any required attachments. Exempt determinations are made in ORRP, usually within one to two weeks.

Expedited review can be performed when there is not greater than minimal risk to subjects and the research falls into one (or more) of nine categories listed in 45 CFR 46.110. Examples of research that can receive expedited review are focus groups, noninvasive procedures (e.g., electrocardiography), use of specimens collected for non-research purposes, and videotaping of teaching methods. Minor changes to research and continuing reviews may also qualify to be reviewed by expedited procedures. Investigators seeking expedited review should complete the appropriate application for IRB review (initial, continuing, or amendment), including the appendix for expedited review, and submit it along with a research proposal and any required attachments.

Expedited review is performed by the IRB Chair and/or an experienced IRB member.

Convened or full board review is required for research that poses greater than minimal risk. These risks include physical, psychological, social, legal, and economic harms. For research requiring convened IRB review, investigators should complete the appropriate application (initial, continuing, or amendment), and submit it along with a research proposal and any required attachments. OSU has four IRBs: Biomedical Sciences, Cancer, Behavioral and Social Sciences, and Western (for industry-sponsored protocols). IRB submission forms and meeting

dates can be found on the ORRP website at <http://www.orrp.ohio-state.edu/>.

Did You Know...?

Use of publicly available data is not human subjects research.

Even if the information contains personal identifiers, if it is not "private" – i.e., the data set can be retrieved by anyone publicly and freely (without special permission) – then the research does not involve human subjects.

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

TANI PRESTAGE, MA, CIP
Education Administrator/Editor
prestage.2@osu.edu

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

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

