



Assistance for Researchers (ORRP Office Hours)

Do you have questions related to IRB forms, policies, or review procedures? ORRP staff are available to help! Please contact our office at (614) 688-8457 to schedule an appointment or to learn about upcoming sessions.

You may also attend office hours designed to help Behavioral and Social Sciences researchers prepare IRB submissions and exemption requests. No appointment is necessary.

215A PAES Building
1-4pm Wednesdays

(Note: Hours are subject to change each semester)

IRB Help Sessions

Did you know that the Office of Responsible Research Practices holds monthly help sessions for investigators, student researchers, and staff? Below is a preview of upcoming sessions scheduled for April and May. If you have any questions, please contact Tani Prestage at (614) 292-0214 or prestage.2@osu.edu.

HUMAN SUBJECTS RESEARCH - APRIL 18

Office of Responsible Research Practices staff will provide an overview of the Quality Improvement (QI) component of Ohio State's

research protection program and site visit process. This session will be held on Wednesday, April 18th from 3 – 4 pm in the Health Sciences Library, Center for Clinical and Translational Sciences, Room 240. Registration is requested.

<http://osp.osu.edu/training/training/eventreg2.cfm?key=1168>

IRB FORMS HELP SESSION - MAY 2

The session is targeted to researchers who submit materials to the Behavioral and Social Sciences IRB. Office of Responsible Research Practices staff will provide an overview of the Initial Review of Human Subjects Research application. This session will be held on Wednesday, May 2nd from 3 – 4 pm in Research Administration, Room 117. Registration is requested.

<http://osp.osu.edu/training/training/eventreg2.cfm?key=1166>

IRB FORMS HELP SESSION - MAY 16

The session is targeted to researchers who submit materials to the Biomedical and Cancer IRBs. Office of Responsible Research Practices staff will provide an overview of the Initial Review of Human Subjects Research application. This session will be held on Wednesday, May 16th from 3 – 4 pm in the Health Sciences Library, Center for Clinical and Translational Sciences, Room 236. Registration is requested.

<http://osp.osu.edu/training/training/eventreg2.cfm?key=1167>

Updated HIPAA Authorization Template and Instructions

The Ohio State University HIPAA Research Authorization template and instructions have been updated and separated into two documents. In addition, the format has been changed to make it easier for investigators to add required information. The form, instructions, and information about the HIPAA Privacy Rule in human subjects research are available on the [HIPAA Authorization](#) web page.

New and Revised HRPP Policies Posted

A new HRPP policy "[Additional Requirements for Clinical Research: ICH-GCP](#)" has been posted on the ORRP web site. This policy describes the requirements, in addition to DHHS and FDA regulations and HRPP policies, for clinical trials involving human subjects to be compliant with ICH-GCP guidance.

HRPP policies, [IRB Actions and Communications](#) and [Expedited Review Procedures](#), have been revised based on recent federal guidance to reflect the IRB's new process for calculating a study's expiration date. The expiration date and approval period are now based on the date an initial submission is approved or, if modifications are required, the date that the modifications are approved. Please note this change affects only initial submissions approved on and after March 1, 2012. Changes are not retroactive. For continuing reviews, the next expiration date and approval period are based on the date that the research is re-approved or modifications are required. For more information and examples, refer to the HRPP policies.

New WIRB Submission Forms

Two new Western IRB (WIRB) submission forms, Initial Review Submission Form and Investigator Submission Form for Multi-Center Protocols, are now available and required for initial submissions beginning March 1, 2012. The new forms can be downloaded from either the ORRP web site: <http://orpp.osu.edu/irb/wirb/index.cfm> or the WIRB web site: <http://www.wirb.com/Pages/DownloadForms.aspx>.

Revised Consent Form Templates

The Ohio State and WIRB consent form templates for clinical research were recently updated. These revisions were necessary to comply with FDA regulations requiring additional disclosures for participants whose research information from applicable clinical trials involving drugs, biologics, or devices will be entered into a databank publicly accessible at ClinicalTrials.gov. The revised templates must be used with new initial submissions beginning March 1, 2012. Investigators are not required to revise consent forms for studies approved prior to March 1st to comply with the new requirements. Please contact Tani Prestage at (614) 292-0214 or prestage.2@osu.edu, or Natisha Denlinger at (614) 688-3330 or denlinger.33@osu.edu, with any questions.

The revised Ohio State Biomedical/Cancer consent form template is available at <http://orpp.osu.edu/irb/consent/index.cfm> and the OSU/WIRB consent template at <http://orpp.osu.edu/irb/wirb/index.cfm>.

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