

## Human Subjects Protection Office (HSPO)

[www.hmc.psu.edu/irb](http://www.hmc.psu.edu/irb) Ph. 717-531-5687

### JANUARY 2009 HSPO UPDATE

#### **Beta Testers Needed for the New IRB eSubmission Tool**

The HSPO will begin testing a new IRB eSubmission tool that is in development by the Office of Research Information Systems for the Penn State Hershey and University Park IRBs. Usability testing occurred in December with a small group of investigators and research coordinators from both campuses. The next step is to conduct beta testing, which is scheduled to be conducted for a two month period, January 19 through March 19, 2009.

Investigators and research coordinators are invited to help beta test the new eSubmission tool. Individuals with various experience levels (beginner vs. advanced computer skills, new vs. experienced IRB submitters) are needed for the beta testing. Beta testers will use the eSubmission tool on-line from their own computers to create an example submission for a new research proposal. Also, individuals who are planning a new research proposal during this time period are sought to use the new eSubmission tool to make the actual IRB submission for review. Individuals who volunteer to participate in the beta testing will receive additional information and instructions to get started.

The goal of this project is to streamline the IRB submission process and implement electronic review capabilities. Rollout of the eSubmission tool for use with new research is anticipated this spring, followed by a phase-in of the tool for other types of IRB issues. If you are interested in participating in the beta testing call Kathleen Hay in the HSPO, 531-5687.

#### **IRB Drop Box Requirement**

As previously announced, effective January 1, 2009, the Institutional Review Board (IRB) requires that all submissions for new and ongoing research be made as electronic files to the *IRB Drop Box*, rather than in paper format. This new requirement is part of the steps being implemented to move toward an electronic submission process. To make a submission, place a folder containing your submission documentation into the *IRB Drop Box* on the server at `\\hershey.med.net\files\HSPO`. For forms requiring signatures, also include a *scanned* PDF copy of the complete, signed form. (Investigator should keep the original signatures in their master study file, available for inspection.) Detailed submission steps are outlined in the [IRB Drop Box Instructions](#) on the web.

#### **FAQs On Quality Improvement Activities**

A new set of Frequently Asked Questions and Answers (FAQs) on quality improvement activities is available from the federal Office for Human Research Protections (OHRP). These FAQs provide guidance on OHRP's current thinking on this topic and should be viewed as recommendations unless specific regulatory requirements are cited. The quality improvement activities FAQs can be accessed at <http://www.hhs.gov/ohrp/qualityfaq.html#q2>.

## **Continuing Education Requirement For Human Subjects Research**

This is a reminder of the requirement, effective November 1, 2008, for continuing education in human participant protection. All investigators and key personnel listed on proposed research projects being reviewed by the IRB must have completed the initial or the continuing education requirement within the past 3 years. Those personnel whose training completion will expire within 90 days of application to the IRB will be required to fulfill the continuing education requirements before IRB approval will be issued. Detailed instructions are provided in the [CITI Course Instructions](#) available on the IRB web site to access the required, on-line training: *CITI Course: Biomedical Research at Penn State, COM & HMC*.

Inquiries regarding the information in this update may be addressed to the HSPO, 531-5687.