

## **June 2011 HSPO Update**

### **Good Clinical Practice and ICH Course Requirement**

As previously announced, the CITI Good Clinical Practice (GCP) course will be required for key personnel involved with human research regulated by the Food and Drug Administration (FDA). Effective July 1, 2011, all key personnel on FDA-regulated research must complete the CITI GCP course and meet the continuing education refresher requirement every 3 years.

The GCP course is available in the Penn State Hershey online CITI curriculum (as part of the Collaborative Institutional Training Initiative). Steps to add this course to existing CITI curriculum are outlined in the [CITI Course Instructions](#), on the web at [www.pennstatehershey.org/irb](http://www.pennstatehershey.org/irb) under Educational Resources.

On July 1, this requirement must be met for all FDA-regulated research before the Institutional Review Board (IRB) will accept new submissions or modifications to add personnel to a study. Questions about this requirement may be addressed to the HSPO, at 717-531-5687 or [hspo@hmc.psu.edu](mailto:hspo@hmc.psu.edu).

### **Updated CITI Course Instructions**

The [CITI Course Instructions](#) were recently revised to provide a simplified enrollment process and include tips for accessing the resources available in CITI. The new instructions (Ver. 5/19/2011) have been posted to [Educational Resources](#) on the IRB website.

### **Revised Radiation Review Form**

The Radiation Review Form, for studies involving radiation procedures specifically for the research, has been updated to provide the IRB and Human Use of Isotope Committee (HUIC) with information needed to facilitate reviews. This form is available at <http://www.pennstatehershey.org/web/irb/home/resources/investigator>.

### **IRB Workshop**

#### **Wednesday, July 13, 2011 - Using the PRAMS Online System for Research**

Hands-on workshops are conducted regularly to cover making online submissions for research, tips for using the system, and how to track/access research records in the Protocol Review and Approval Management System. The sessions are held in the computer room C2610A. To register, please call the HSPO at 531-5687.

For help with questions about this HSPO Update, contact the HSPO at 531-5687 or at [hspo@hmc.psu.edu](mailto:hspo@hmc.psu.edu).