Human Subjects Protection Office (HSPO)
Ph. 717-531-5687 **www.pennstatehershey.org/web/irb**

July 2013 HSPO Update

IRB Review Delays

As you may know the institution is preparing for the transition to the new Centralized Application Tracking System (CATS), which will replace the IRB data management system (PRAMS) later this year. The HSPO has been concentrating a great deal of its efforts toward updating processes and meeting the requirements for the new system. This will continue to require much attention in order to be ready for implementation within a few months.

During this time period, please be aware of the potential for delays in IRB review. It is important that you let the HSPO staff know if you currently have a new application, modification or other issue that is pending review and must be addressed by a specific deadline. Your patience is appreciated during the next few months as we all work to meet additional requirements and prepare for the new system. Thank you for your cooperation.

CITI Course Temporarily Unavailable

The CITI Program has announced that starting Monday, July 29 at 11 a.m., Eastern Daylight Time, the website will be unavailable for approximately two to three days to complete a major software upgrade. Researchers who need to complete a CITI course or renewal to meet an IRB requirement should be aware of this downtime and plan accordingly. The CITI courses are available at https://www.citiprogram.org/default.asp.

Scientific Review Requirement for Research

Researchers are reminded of the new scientific review requirement for investigator-written human research studies, effective September 1, 2012. Investigator-written studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. This scientific review requirement may be fulfilled by one of the following:

- External peer-review process (e.g., research studies funded by an NIH grant)

- Scientific review by department/institute committees (available in these areas):
  - Anesthesiology
  - Cancer Institute
  - Family and Community Medicine
  - Neurosurgery
  - Neurology
  - Opthalmology
  - Psychiatry

- Scientific review by the Clinical Research Center (CRC) Advisory Committee
  - The CRC Advisory Committee should be used by investigators from departments without a scientific review process. This committee meets the first Wednesday of each month. An Application for Scientific Review is due by the 25th to be included on the next CRC agenda. For the IRB submission, upload the Preliminary Scientific Review Checklist signed by CRC chair as documentation of scientific review.

New Policy – Reportable New Information

In May, a Reportable New Information policy was implemented for submitting information to the IRB, including new or increased risks, harms experienced, audit reports, failure to follow the protocol, and other information for research studies.

- See Reportable New Information (RNI) Process on the IRB web site, Investigator Resources page, for links to the policy, RNI form, and template.
    - The old problem report form and tracking logs will no longer be used.
    - Please note: When submitting revised investigator brochures that include new risks information and consent form changes, the RNI form must be submitted, along with a Modification request, and a revised consent form.
- Workshops are being offered to explain the new policy and reporting process.

IRB Workshops

Additional topics have been added to the research coordinator series, which now includes the following workshops:

- IRB Process Overview for Researchers
- Informed Consent Process for Research
- Reportable New Information in Research
- Research Document Management: Guidance for Maintaining Regulatory Documents & Subject Records

Participants are eligible to receive continuing education credit for each workshop attended, including patient safety continuing medical education credits or nursing education credits where applicable. Visit the IRB Educational Resources page for a list of available dates.

If you have any questions about information in this HSPO Update,
please contact the HSPO at 531-5687 or at hspo@hmc.psu.edu.