

## October 2010 HSPO Update

### IRB Submissions Screened for Completeness

The HSPO will begin screening incoming research eSubmissions to confirm completeness before the materials are accepted and forwarded to the IRB for review. New submissions will not be accepted until all of the required information and materials necessary for the board to conduct a review have been provided. Incomplete submission will be returned to investigators with instructions to address the missing elements and to re-submit.

- Effective November 1, screening will commence for new submissions for inclusion of:
  - Completed signatures pages
  - Completed continuing education for all key research personnel
  - A research protocol document and consent form(s) for full board studies
- As of January 1, 2011 new submissions will be screened for inclusion of all of the required documents before acceptance, including the following when applicable:
  - Documentation from other committees (conflicts of interest, scientific review, radioisotopes use)
  - Grants
  - Consent form(s)
  - Recruitment materials
  - Investigator Brochure

### Changes to Submission Signature Requirements

- The IRB will accept the following for the principal investigator's department chair signature:
  - Department chair
  - Department Research Vice-chair
  - Acting Department chair
- The IRB will no longer require departmental level signatures for the key personnel on a study.

Revised [Assurance Statement Signature Pages](#) reflecting this change are available on the IRB web site for use with new submissions.

### Older Consent Form Header Updates

The HSPO has posted step-by-step instructions for updating an older consent form to the new header and approval stamp box format. The instructions are available on the IRB web site, Investigator Resources page; see [Steps to Update a Consent Form Header and Approval Stamp Box](#).

*NOTE: Older consent forms do not need to be updated until the next time a Modification Request is needed to revise the form for other reasons.*

### New CITI Course Access Instructions

New *illustrated* instructions are now available on the IRB web site to help investigators *access and register* for the applicable course in the CITI program. Research coordinators may find the [CITI Course Quick Access Steps](#) useful to distribute when informing investigators who need to complete the human research protection course requirements.

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### Updated Problem Reporting Policy and Logs

An update was made to the policy for [Reporting and Review of Unanticipated Problems Involving Risks to Participants or Others](#), revised 9/27/2010 to reflect that:

- In addition to previously stated policy requirements (B.1. a-h), investigators must also report:
  - i. U.S. Food and Drug Administration Form 483 or findings from audits performed by other governing regulatory agencies (or authority); and
  - j. Any report provided to investigators for audits performed by an agency external to study sponsors or their authorized representatives
- Also, the following problem report logs were revised to add the column "Date Event Reported to Study Staff":
  - [Problem Accumulative Tracking Log](#)
  - [Other Event/problem Accumulative Tracking Log](#)

*NOTE: It is not necessary to revise existing logs already in progress for a study.*

### Updated Policy for Recruitment of Research Participants

Revisions have been made to consolidate the policies for identifying, advertising, contacting and providing recruitment incentives/compensation into one document, [Recruitment of Research Participants](#).

In addition, a change was made regarding advertisements on internet web sites, to be consistent with Food and Drug Administration guidance. IRB review and approval of listings of research or clinical trials on the internet is not required for *simple listings* (when the web system format limits the information provided to basic trial information), but is necessary when posting a *descriptive listing*. See the revised policy, dated 8-06-2010, for more details and what information qualifies as a simple listing.

### Guidance on Withdrawal of Subjects from Research

The following guidance from Office of Human Research Protections (OHRP) and FDA clarifies what may be done with regard to data retention when a subject is withdrawn from research:

- OHRP: "Guidance on Withdrawal of Subjects from Research: Data Retention and other Related Issues" available at: <http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html>
- FDA: "Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials" at: <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm>

If you have any questions about this HSPO Update, contact the HSPO at 531-5687 or at [hspo@hmc.psu.edu](mailto:hspo@hmc.psu.edu).