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December 2010 HSPO Update

IRB Submissions Screened for Completeness

As previously announced, all incoming research eSubmissions are screened by the HSPO to confirm completeness before the materials are accepted and forwarded to the IRB for review. Initial screening has included verification of signatures, education for all key research personnel, and protocol and consent documentation. Effective January 1, 2011, all new eSubmissions will be screened for inclusion of <u>all</u> of the required documents before acceptance, including:

- Completed and current dated assurance statements/signature pages
- Completed continuing education for all key research personnel
- A research protocol document and consent form(s) for full board studies
- Documentation from other committees (conflict of interest, scientific review, radioisotopes use)
- Grants
- Consent form(s)
- Recruitment materials
- Investigator Brochure

New eSubmissions will not be accepted until all of the required information and materials necessary for the board to conduct a review have been provided. Incomplete eSubmissions will be returned to investigators with instructions to address the missing elements and to re-submit.

TIPS: Before making an IRB eSubmission, research staff should verify that the following are met:

- CIRC Investigators with a conflict of interest (COI) must have updated their COINS disclosure to
 include the new protocol number and COI details. Research coordinators should check each
 investigator's COI statement on the signature page and remind any investigator with a COI to
 update their COINS disclosure (http://coins.psu.edu) before the study is submitted.*
- SRC Approval memo from the Scientific Review Committee is required, if applicable, before the eSubmission will be accepted.
- HUIC A copy of the Radiation Review Form submitted to Steven King must be included with the eSubmission.**
- IBC A pending number is sufficient for eSubmission.***

*CIRC - Concurrent reviews may occur but IRB approval will not be granted until the CIRC review is completed. If the COI involves equity, IRB review may be postponed until after the CIRC review.

**HUIC - Concurrent reviews may occur but IRB approval will not be granted until HUIC review is completed. If the research involves an <u>investigational</u> radiation procedure or drug, then HUIC review may need to be completed before IRB review.

***IBC - If the study involves gene transfer or recombinant or infectious materials, IRB review may be postponed until after IBC review.

Human Subjects Protection Office (HSPO)

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Updated Assurance Statements/Signature Pages

The assurance statements/signature pages were revised (Ver. 12/30/10) as follows:

- Require the study title and sponsor name (if applicable) listed on each page
- Principal investigator and all key personnel must <u>initial</u> a statement to indicate what their conflict of interest (COI) status is with regard to the research
- All individuals must include the date they signed the form with their signatures
- Web address included for making COI reports/updates to the COINS system
- An instructional reminder was included to explain that for personnel additions, the signatures
 are needed only for the new investigators being added to the study

Research staff should begin using these new signature pages immediately for new research submissions and when submitting modifications for personnel changes.

Please visit the IRB web site to obtain the updated signature pages for your next submission. (Call the HSPO if you have guestions about signatures already in progress for a new submission.)

Documentation Available in PRAMS for All Research

The HSPO would like to remind research staff that IRB documentation is available in PRAMS for <u>all</u> current research, for both eSubmission studies *and* research studies that were submitted by a previous method (e.g., paper or drop box). The available documentation includes IRB approval memos, IRB minutes, and the approved stamped consent form(s). These documents may be accessed under the 'Documents' tab when logged into the study record within PRAMS (at http://www.prams.psu.edu).

Steps for accessing documentation and using other resources in PRAMS are part of the topics covered in the IRB eSubmission Workshops. See Educational Resources on the IRB website for workshop dates, or call the HSPO staff for assistance using PRAMS or any guestions you may have.

Updated CITI Course Access Instructions

The <u>CITI Course Quick Access Steps</u> have been updated (Version 12/29/2010) to provide additional explanation on how to access the refresher course for continuing education and other clarifications. Please use this latest version when distributing the information to investigators who need to complete the human research protection course requirements.

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