November 2014 HSPO Update

Revised Policy for Data Security and Integrity

Updates have been made to the IRB SOP Addendum policy: Security and Integrity of Human Research Data. The revisions will be effective December 1. The revised policy is now available on the IRB website, under Resources/Investigator Resources, Security and Integrity of Human Research Data.

New information is included in the policy to define PSH researchers and external researchers, define a new 2-level categorization for data, and clarify requirements for data transfer and/or sharing. Information on the updated policy will be provided in the November 18th IRB seminar, listed below.

IRB Workshops

IRB Policy on the Security and Integrity of Human Research Data
Tuesday, November 18, 1:00 p.m. – 2:00 p.m.
Lecture Room D, #C7619
Note: If interested in CME/CE credit for continuing education attendees must:
-Contact the HSPO (x5687) to pre-register for this session, and
-Swipe the ID badge card reader upon arrival to confirm attendance

Reportable New Information workshop
Thursday, Dec. 18, 1:30 p.m. – 3:00 p.m.
Pre-registration is required due to limited space. Contact the HSPO (x5687) to register.

CATS IRB – CATS IRB Training and drop in Help Hours are posted on the web.

Important Reminder Regarding Written Documentation of Consent

When the signature section of the consent form is being completed, the signature line must be filled in only by the person signing the form. Each individual signing the form must print his/her name, sign, date and time his/her own signature line, including the:

- Person who is obtaining consent
- Subject or legally authorized representative providing consent
- Witness, if applicable

No one else may enter any detail on the signature line or fill in anything missing.
This is based on recent draft FDA guidance and best practices. The "SOP HRP-091 – Written Documentation of Consent" is being updated to reflect this clarification.

CITI IRB Training Access to be Updated

Penn State Hershey is coordinating a single sign-on (SSO) process with the host of the CITI web site for IRB training, so that researchers will have the convenience of using their PSU ID and password to log in. The CITI site already includes a 'Log in through my institution/Log in via SSO' link, but until the technical work is complete any Penn State Hershey researchers using this link will be unable to see their coursework history. Penn State Hershey researchers are asked to continue using their original CITI ID and password until further notice. An announcement will be made when the Penn State Hershey single sign-on process for CITI is operational. Meanwhile, the CITI Course Instructions for access have been updated with this clarification.

CATS IRB Updates

Updated Investigator Manual – The June 2014 revision of the Investigator Manual includes an expanded HIPAA section, instructions for choosing protocol and consent form templates, instructions for submitting protocol exceptions, and the policy for submission and review of IND/IDE safety reports.

Additional Print Option - Two print options are now available in CATS IRB under the My Current Actions section, and a CATS IRB FAQ explains how to use these features.
- Printer Version – generates a PDF of the submission form only
- Print Materials – generates a PDF of all the documents that were added to CATS IRB

CATS IRB Reminders:
- Name the documents you add to CATS IRB carefully to be indicative of what the document is (e.g. protocol, consent form, data instrument), keeping in mind that the name you choose is what appears on the IRB memo. Do not use any periods in a document name or the study title, because the system will recognize a period as the end and truncate the rest of the name. Finally, remember that the 'short title' entered in your CATS IRB submission is what will list in the IRB memo for the study title.
- For each submission use the current template versions available in the CATS IRB Library, and keep the template version date listed in the footer.
- When making modifications or continuing review submissions, use caution in selecting the combined MODCR submission. Select a combined submission only if you do not need approval for one issue before the other. It is recommended a combined MODCR be used only for minor changes, not amendments to a study.

Department Representatives for IRB Training Lookup

Each department has identified a staff member to be given CATS IRB system access to look up IRB training information. This new role is being added to help address departmental faculty and staff member needs for this type of information. The technical requirements have been identified and programming is underway to create a new CATS IRB system role for this process. An announcement will be made once the departmental representatives are trained and the process is ready to implement.

For questions regarding information in this HSPO Update contact the HSPO at 531-5687.