

March 2010 HSPO Update

Revised Consent Form Templates

New versions of the consent form and parental permission templates have been posted on the IRB website, Investigator Resources page, under [Informed Consent](#). The updated versions include:

- Simplified language and formatting, including section headings that are in question format
- Cost section language for clinical trials
- Additional clarifications and wording for the signature sections

The addendum to consent templates and instructions for preparing consent forms were also updated.

Use of the revised templates for new studies will be required effective April 1, 2010. (Ongoing studies, and new studies submitted before the April 1 deadline, do not need to be updated to the new format.)

Workshop: These changes will be covered in a March 17 workshop, [Writing Consent Forms for Research](#).

Electronic IRB Document Distribution

As of April 1, 2010, in order to improve efficiency and facilitate record keeping, the HSPO will be maintaining and distributing IRB documents via the PRAMS system, and will no longer send print copies or e-mail attachments. Applicable documents will be signed and stamped electronically. Investigators will receive an e-mail notice when the study documents are posted and available for access, with instructions and a link to log in to PRAMS to access IRB communications, minutes, stamped consent forms and any other IRB documentation. This applies to IRB documentation for both eSubmission and non-eSubmission studies.

PRAMS eSubmission Tips

Follow these tips when making on-line submissions using the PRAMS IRB eSubmission tool.

- If needed, you can update your Penn State account password at the badge reader in the library.
- For your first eSubmission, access PRAMS via the IRB web site [Investigator Resources](#) page, under Making an IRB Submission, where you will find Submission Instructions, Navigation Tips, and a link to PRAMS, including instructions if you want to access from home.
- When adding personnel in PRAMS, assign them a role of PI, Co-investigator or Project Coordinator, and assign the 'Advisor' role to anyone else who may need to access the eSubmission.
- When uploading a document to PRAMS, always provide information in the *Additional Detail* field.
- Remember to scan or save your signature pages as PDF documents, then upload them to PRAMS.
- After submitting, the eSubmission is locked from edits unless the IRB returns it to you for changes.
 - During review you will need to use PRAMS to address any edits the IRB requires.
 - If you receive an e-mail notice to address revisions, make your edits working from the highest to lowest question # (it's less confusing if your edits cause the numbering scheme to change).
- After an eSubmission study is approved, use PRAMS when a Modification/Amendment is needed.
 - If you upload a *revised* document, always select the prior version in PRAMS and [Replace it](#).
- Continue to use the IRB Drop Box (off line) to submit any problems, protocol deviations/exceptions and miscellaneous issues until notified that a PRAMS tool is available for these submissions.
- To submit progress reports for continuing review, follow the instructions in your e-mail notification. (A PRAMS eSubmission process is pending.)

Workshops: See the IRB website, [Educational Resources](#), for a list of eSubmission workshop dates.

Please contact the HSPO at 717- 531-5687 (hspo@hmc.psu.edu) with any questions.