

## May 2014 HSPO Update

### Converting a Study from PRAMS to CATS IRB

Special care is needed when setting up a CATS IRB submission to complete the conversion steps, which are required at the first modification or continuation review for a converted study. Specific selections are necessary so that CATS creates a submission with all the areas that must be accessed for the conversion. Once CATS creates the structure of the submission to the chosen specifications, it is not possible to add or delete sections if a required selection was missed. The following resources are available to help when creating a conversion submission.

- The step-by-step instructions and templates below provide detailed guidance.
- CATS IRB Help Hours are held weekly for individualized computer assistance.
- Or call the HSPO (x5687), if needed, before starting a conversion submission.

#### Step-by-step instructions and templates for conversion

- Obtain these documents from the CATS IRB Library at [irb.psu.edu](http://irb.psu.edu), by selecting 'IRB' (beside Home), IRB Library, and the Templates tab.
  - **HRP 503b - Next Steps for Converted Studies – For IRB Researchers**
  - **HRP 503d - How to Upload a Protocol for a Converted Study HY**
    - **Protocol Site Addendum template (HRP503j)** – see the table in HRP 503d above to determine if you will need to prepare and upload this document
    - **Consent forms** – also see the table in HRP 503d for steps to update a consent form to the CATS IRB format, if applicable
- **HRP 509 – Study Team Member Qualification Template** – This is a new document that must be created for all studies in CATS IRB and uploaded with the conversion submission.

### CATS IRB Help Hours

Open computer lab hours are available weekly for help with CATS IRB submissions, including help to complete the steps for a PRAMS study that converted to CATS. Check the campus calendar or IRB website [Educational Resources](#) for dates and times.

### CATS IRB Reminders

- **Check the Home page for the latest information including:**
  - News and Alerts, such as downtime notices
    - **Please note** - CATS IRB will be unavailable May 8, 2:00 a.m. – 7:00 a.m.
  - Frequently Asked Questions and Release Notes
- **Check the IRB Library for the latest template versions**
  - Including recent updates to HRP 503b – How to Upload a Protocol for a Converted Study (HY), with simplified instructions and protocol requirements.

- **Set a Primary Contact and PI Proxy for each study**
  - Set these at the Study level (not in Modification or other follow-on submission).
    - Primary Contact** - someone to receive notices along with PI
    - PI Proxy** – assigns study staff member(s) to submit on the PI's behalf
  - For instructions, see the online **Help** link and the **IRB Submission Guide**.
- **Name Your Documents Carefully**

When you add or update a document, keep in mind that the name you choose for a document is how it will be listed in the IRB correspondence.
- **Don't forget the Submit step**
  - Several researchers have called about the status of a submission, only to find out that they did not yet *submit* to the IRB. When ready to submit follow these steps:
    - Select **Finish** to complete the submission preparation process
    - On the next screen, select **Submit** from the My Current Actions list on the left. (Note: Only the PI or PI Proxy will see the Submit action available.)
  - Check the flow diagram to see where the submission is in the review process.

This has not been submitted to the IRB



This submission is undergoing Pre-review



- **Tips for Submitting Continuation Review (CR) in CATS IRB**
  - Question 4 of the CR submission form in CATS gathers information about study conditions to affirm by checkmark if true.
  - In question 5, the only documents that need to be uploaded are:
    - 1) materials or explanations to support any *unchecked* items for question 4; and
    - 2) a sponsor's progress/annual report, data and safety monitoring board (DSMB) report\*, publications, etc.It is not necessary to upload consent forms or other study documents in question 5, unless needed to support an unchecked item in question 4.
    - \*Please note: If the study has a DSMB, you must submit either the most recent report or the sponsor's explanation of why the DSMB report is not available.

- **CATS IRB User Basics**

- In CATS IRB ([irb.psu.edu](http://irb.psu.edu)), the **My Inbox** page shows any studies needing your action.
- To find other studies, select **IRB** (beside Home) for the IRB Submissions page.
  - Sort through the studies by Tabs based on status (i.e. In Review, Active)
- The resources and templates needed for researchers are available in the **IRB Library**:
  - GENERAL tab – contains the Investigator Manual
  - TEMPLATES tab – contains the templates needed for a submission
- Link to the **IRB Study Submission Guide** for instructions to create/edit a study, submit modifications and follow-on submissions, assign PI Proxy(ies) and more.
- Link to the **Help** shortcut for an introduction to CATS and additional help topics.
- For inquires, Support Contacts are included on the page footers and the Home page.

## **New CATS IRB Process for Ancillary Reviews**

The IRB is now assigning ancillary review in CATS IRB when a study requires it. Common types of ancillary review include:

- **Conflicts of Interest Review** – required if a conflict of interest is reported
- **Anatomic Pathology** – for use of human tissue for research
- **Human Use of Radioisotopes** – if radiation procedures are included (SOC or research)
- **Institutional Biosafety Committee** – for biological safety/biohazards review

### Procedures

- Researchers submit a CATS IRB application with applicable forms\* and/or information in the protocol/protocol site addendum (\*including the Radiation Review Form and/or Use of Human Tissue for Research Form if applicable)
- HSPO pre-reviewers set the ancillary review activity needed in CATS IRB. (This sends an email to the ancillary committee to conduct the ancillary review for this submission.)
- Ancillary committee completes the review and submits a report in CATS IRB via the ancillary review activity

## **HSPO Website Updates:**

- Recent updates to the HSPO website ([www.pennstatehershey.org/irb](http://www.pennstatehershey.org/irb)) include:
  - Addition of a direct link to access CATS IRB
  - Reorganization of the Investigator Resources page
    - New link to *Forms and Instructions Not Available in CATS IRB*
  - Recently updated forms:
    - Radiation Review Form
    - Use of Human Tissue for Research Form