

September 2015 HSPO Update

HRPP Toolkit Updates - The following changes were made during recent updates to the IRB Toolkit:

- HRP-103 Investigator Manual - updated content; Manual is now accessible in Help Center
- Protocol template updates – All of the protocol templates were updated and include revised instructions, formatting changes, and some combined sections. The following new template was added:
 - HRP-596 Protocol for Human Subject Research - Chart Review and or Analysis of Existing Restricted Data Set Study
- HRP-509 Study Team Member Qualifications Template – This template was updated with a reminder to not enable track changes when modifying the document.
- Consent Form Templates - Most of the consent form templates were revised with mandatory wording changes and other revisions, including:
 - HRP-580 HSPO Consent Form template – revised instructions and updated text in sections 3, 7b, 8a, 8b, 9, 12, assent and optional parts
 - HRP-584 Consent Guidance for Exempt Research - revised as guidance
 - HRP-585 and 586 HSPO Summary Explanation templates - updated

Researchers are reminded to always use the CATS IRB Library to obtain the latest version of template documents needed when preparing an IRB submission.

Tips for Document Version Numbering in CATS IRB

If providing a version when naming documents in CATS IRB, remember that the version field is numeric only and accepts integers, but no dates, symbols or other characters (which will produce erroneous results). A request has been submitted to allow for dates in a future CATS IRB release; however, in the meantime tips for managing the version field follow.

- **Automatic version numbers** - For each document uploaded, leave the version field blank and CATS IRB will automatically insert a version number beginning with '01' and automatically update the version field each time the document is updated.
- **Researcher controlled version numbers** - If desired, researchers may specify a document version number in integer format. However, this process must be managed for all subsequent updates of a document. If a document is updated and a version number forgotten (or entered incorrectly, such as with a date) the CATS IRB system will revert to automatic version numbers.

STAR Submission Questions

The Created STAR Submission has been activated in the CATS IRB system, so researchers will now need to indicate if a STAR submission is also needed when creating a new submission. For more information or help answering any STAR questions please contact the [Clinical Trials Office](#).

For questions regarding this update contact the Human Subjects Protection Office at 531-5687.