Ascension

Ascension Wisconsin

Research Integrity and Protection Newsletter

August 2019

IRB Approval Stamps

The IRB applies an approval stamp to consent documents (including verbal scripts or information sheets) and HIPAA authorization forms. The approval stamp includes an "Activation Date". This is the date that the IRB released the final approval to the study team, and they get access to begin using the document. This date may or may not be the same as the initial approval date.

Example:
A study is approved pending IRB required modifications on 7/1/19; the study approval date is 7/1/19.
However, all required modifications are complete and the final IRB approval letter is sent on 7/30/19.
Therefore, the consent form will be stamped with the "Activation Date" of 7/30/19.

The IRB SOP-503 Post-Review Approval Completion has recently been updated to reflect this process.

As a reminder, the IRB only issues stamped consent and HIPAA documents at the time of initial approval or with changes to the document. See the Consent Form Approval Stamp Memo for more details.

REQM Report Revisions Coming Soon!

We are updating the format of the REQM routine review report in response to the recent survey and other feedback.

What you'll see:

- Cleaner and "less wordy" format
- Easier to identify required actions
- Applicable references included for each observation, including federal regulation; state law; ICH GCP; Institutional, IRB or department SOPs; and the protocol or other study requirements

We will begin to pilot the new format in August.

We appreciate your feedback to help improve REQM processes and tools. If you have comments on this new format or anything else REQM related, let us know at RIPO@Ascension.org or contact Bridget Psicihulis.

UPDATE: Research HIPAA Authorization

There was a minor change to the HIPAA Authorization to add "research partners" as an entity who might see and use PHI. The form has been updated on our website and in Mentor; the Spanish language version will be updated soon.

As a reminder, always go to the website or Mentor to ensure you use the most current forms and templates.

MENTOR UPDATES

NEW: Amendment Number on Approval Letter

Mentor assigns a number to each amendment received for a protocol. This number will now display in the header of the approval letter to help with tracking and clarity of approvals. *(Note, this is not the same as the Sponsor's amendment number)*

NEW: Protocol Activity Log

Study teams now have access to view the protocol activity log by clicking the "Logs" link in the top right of the main protocol page. This log will display actions such as notification sent, PI signature requests, etc.

NEW: Print Protocol reports to PDF

There is now a "print to pdf" link on each protocol report (cont. reviews, amendments, etc.) that will generate a pdf of just that report. Study teams can use this to easily document what was submitted to the IRB for each report.

UPDATED: PI Signature Required for Submission

The PI signature will be required for Safety Updates and Noncompliance reports before the Submission option is available, making the functionality consistent with other report types. Additionally, any information or materials marked as "required" for a submission must be complete in Mentor before the PI signature request option is available.

REMOVED: Protocol Review Complete Notification

Study teams will no longer receive a notification when a reviewer completes a review. Receiving this message added additional administrative work for study teams, with no real added value.