IRB Approval of Consent Documents

April 4, 2016

The Ascension Wisconsin IRB does not include expiration dates on IRB approved consent forms.

Rationale:

- Neither the Food and Drug Administration (FDA) or the Office for Human Research Protection (OHRP) mandate that the IRB stamp the final IRB approved copy of the consent document.
- Using an expired version of the consent document when obtaining consent is a common deviation. Most often, the content of the consent is identical to the approved version, even though the approval "stamp" indicates that it is expired.
- The approval period is for the study overall and the expiration date is documented in the IRB approval notice. Including the expiration date on the consent form does not ensure it is the most current version, nor does it add to the protection of research participants.

Anticipated benefits:

- This process will save time for Principle Investigators (PI), study staff and IRB staff since consent forms will no longer need to be re-approved at the time of continuing review as the consent approval will remain valid until an amendment revises the content of the consent form.
- We anticipate this change will benefit PIs by reducing minor noncompliance deviations. Often times the content in the consent has not changed but the form has expired.

PROCEDURES:

The IRB issues approved consent forms as a pdf with an IRB "stamp" that includes the IRB number and Activation date, which is the date that the consent form was released for use by the IRB. This date will be the same as the activation/release date for the study but may vary from the study approval date, depending on whether modifications were required before the final IRB approval was released.

IRB approved consent forms do not include an expiration date. The approval of the consent form is valid until the study is closed or until the consent form is updated, whichever occurs first. Therefore, the IRB issues approved consent forms only when changes are made. The revised consent form IRB "stamp" includes the Activation date of the current revision approval. The PI/ research staff is responsible for including or updating any other versioning they include on the consent form.

The IRB approved consent forms are available in Mentor and are attached to IRB approval notifications when the initial or modified consent form is approved.

Examples:

- New Research Study: The IRB will issue the approved consent form at the time of the initial review final approval (consent activation date). This consent form is approved until the study is closed or until the consent form is amended. This consent form will not have an expiration date.
- Amendment with Changes to the Consent Form: The IRB will issue a new, approved consent form with the amendment approval (consent form activation date). This consent form is approved until the study is closed or until amended again. The consent form will not have an expiration date.
- Continuing Review: At the time the continuing report is submitted, the study team should submit the current approved consent form that they are using. No new consent form will be issued with the continuing review approval. The current approved consent form remains valid until the study is closed or until the consent form is amended. If changes need to be made to the consent form at the time of the continuing review, they must be submitted with an amendment.

Transition Plan

- New Protocol Approvals: The new IRB approval stamp will be used the approved consent forms for all new protocols approved after March 1, 2016.
- Amendment that Include Changes to the Consent Form: If an amendment requires a change to the consent form and the current IRB approved consent has the old IRB stamp, a new consent form will be with the new IRB stamp will be issued when the amendment is approved, per the process above. The stamp will include the new activation date for the amendment approval.
  Amendments that are submitted only to update the IRB approval stamp will not be accepted.
- Continuing Review: At the time of continuing review, a new consent form will be issued with the new format of IRB stamp for any studies that are open to enrollment and the current IRB approved consent form has the old version of the stamp.
  This will be done one time in order to bring all IRB approved consent forms into compliance with this new process.

Reminders

- The Investigator is responsible for ensuring the most current IRB approved consent form is used when obtaining consent.
- It is the responsibility of the principal investigator and the research study team to monitor the expiration date of the *study* to ensure continuing approval.

Please contact IRB staff if you have any questions about this statement.