

 IRB Approval of Consent Documents

*April 16, 2020*

The National Marrow Donor Program (NMDP) 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 expired consent is identical to the approved version, even though the approval period on the form 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, the content in the consent has not changed, but the form has expired.

**PROCEDURES:**

The IRB issues approved consent forms with an approval date that is the same as the final approval date for the study; this also applies to template consent forms for multi-site studies. The approval date for the consent form of a participating site on a multi-site study where the NMDP IRB serves as the site’s IRB of record will be the date that the site’s consent form is approved by the IRB.

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 includes the approval 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 when submitting the consent form for IRB approval. The IRB approved consent forms 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. 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. 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 review application is submitted, the study team should submit the current approved consent form that they are using. If the study team wishes to make changes to the consent form, they may submit changes at the time of continuing review. If no changes are made to the consent form at the time of continuing review, no new consent form will be issued with the continuing review; the current approved consent form remains valid until the study is closed or until the consent form is amended. If changes to the consent form are approved at the time of continuing review, the IRB will issue a new, approved consent form with the same approval date as the study continuing review approval date.

**Transition Plan**

* New Protocol Approvals: Consent forms for all new protocols approved on or after April 16, 2020 will not include an expiration date.
* Amendment that Includes Changes to the Consent Form: If an amendment requires a change to the consent form, and the current IRB approved consent has an expiration date, a new consent form will be issued when the amendment is approved, per the process above. The new consent form will include the amendment approval date and no expiration date.
	+ Amendments that are submitted only to update the IRB approval period on the consent form will not be accepted.
* Continuing Review: At the time of continuing review, if the current IRB approved consent form includes the expiration date, a new consent form will be issued with the expiration date removed for any studies that are open to enrollment.
	+ 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 (**IRBstaff@nmdp.org**) if* you have any questions.