MCW/FH HRPP Updates: Revised Consent Templates

On January 17, 2018 DHHS announced a six-month delay of implementation of the 2018 Common Rule changes. The new date for implementation and compliance of these changes is **July 19, 2018**.

Although this delay means that MCW/FH IRB Office cannot apply most of the provisions within the revised Common Rule, the IRB Office is moving forward in revising our consent templates to adopt the 2018 Common Rule revisions ahead of the new implementation and compliance.

MCW/FH HRPP decided to incorporate these informed consent revisions as these changes do not conflict with the current Common Rule and reflects a best practice.

Scope of Impact to your Research:

New projects which are currently in negotiations with Sponsors, or in a pre-submission state in eBridge and have not been submitted to the IRB are *strongly encouraged* to update their draft consents, and utilize the January 26, 2018 consent form templates as soon as possible to ensure compliance with the July 19th implementation of the 2018 Common Rule.

Visit the IRB Consent Form Templates webpage to access and download these updated documents.

Updated! IRB Policies and Procedures:

1. **IRB SOP: Informed Consent and Documentation for Human Subject Research**
   a. Updated to incorporate the new elements of informed consent from the 2018 Common Rule changes as described below in the templates.

Updated! Informed Consent Templates:

1. **Consent & Consent/Assent Form Templates** – The following templates have been revised:

Clinical Intervention Minimal Risk Banking NCI-Local	Exception to Informed Consent (EFIC) Emergency Use Trial Partners	Clinical Intervention – Consent/Assent Minimal Risk Consent/Assent

The following new or revised elements to the consent form have been added to these templates as described in the 2018 Common Rule changes. Other minor revisions have been incorporated based upon feedback from our research teams.

New Introduction – 2018 Common Rule requires informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

Revised **C4 Reproductive Risks –** updated blue language options to add in language restricting sperm or egg donation by subjects. Also added language if subjects or partners become pregnant, they will be asked to be followed for safety reasons. Revised

Posted: January 26, 2018