

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 IRB-Required Template language is now locked** – Template language in black type is now locked on all MCW/FH ICF templates. Some sections of the form can be removed if they do not apply to a specific study and Sample language, which can be used, modified, or deleted as appropriate for your project, is in blue type.
- **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 Section E2 Use of Data or Biospecimens - New** required language has been added if the research involves the collection of identifiable private information or identifiable biospecimens. *Once all personal identification is removed from your health information <<and/or biospecimens>>, the information <<and/or biospecimens>> may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative*
 - **Revised Section D2** A *new* option has been added to this section if a project involves biospecimens. *Sponsor, other researchers, or research companies may patent or sell products, discoveries and data or information that result from this research. Neither Sponsor nor <PI> will pay you if this happens. You will not receive any payment or commercial rights for products, data, discoveries, or materials gained or produced from your <health information/ specify biospecimens>.*
 - **NEW Section D4** – New language has been included in this section for projects where clinical relevant information will be disclosed. *Clinically relevant results, including individual results, [will / will not] be disclosed to you. [if results will be disclosed, describe the conditions for disclosure]*
 - **NEW A statement if the research will or might include whole genome sequencing (WGS) (if applicable)** – *MCW/FH IRB's genetic testing consent module has been added to the ICF template for projects which will or might include WGS*
2. **Assent Form Template** – The assent template's formatting has been updated to match all MCW/FH informed consent templates. No additional changes were made to this document.