

MCW IRB Office Revised Common Rule Transition Plan

The MCW IRB Office will be applying the revised Common Rule to all new research effective January 21, 2019. At the same time, the MCW IRB Office will be transitioning all currently approved research projects to comply with the revised Common Rule.

MCW IRB Office's transition plan is based on one of the possible transition plans and timelines that OHRP has developed and posted on their website.

In anticipation of these changes going into effect in 2019, the MCW IRB Office has been updating the eBridge PRO SmartForm along with revising the consent form templates to incorporate all the revised changes that apply at MCW.

- x For Minimal Risk projects with a consent form: these projects must update the consent form with the next amendment or the next CPR (if the CPR is reviewed after 01/21/2019 AND before the next amendment).
 - o Currently approved research projects with a Continuing Progress Report (CPR) due can update the consent form with the CPR to the new templates – This is a one-time exception to ensure compliance with the Revised Common Rule.
- x For Minimal Risk projects who have been granted a waiver of consent: these projects should submit an amendment to complete new questions which have been incorporated to the eBridge PRO SmartForm in support of the Revised Common Rule.

Research teams should submit their amendment before their next CPR to be reviewed over the course of 2019-2020

 - o Amendments will ensure the project is reviewed under the appropriate research categories and level of risk given the expansion of exemption categories along with addressing the new question to be issued a waiver of consent.