



## Wright State University IRB Guidelines for Implementing Revised Common Rule

The Revised Common Rule went into effect on January 21, 2019.

- If your study was approved before January 21, 2019 and is federally funded or FDA regulated, then the Pre-2018 Common Rule regulations will continue to apply to your study.
- If the approval date of your study is on or after January 21, 2019 and your study is federally funded, then you must adhere to the Revised Common Rule. This includes key information summary in the consent form, new consent elements and the revised continuing review requirements.
- If your study is funded by the Department of Justice (DOJ) then the Pre-2018 Common Rule will still apply as DOJ has not yet signed onto the Revised Common Rule.
- If the approval date of your study is on or after January 21, 2019 and your study is FDA regulated, then you must adhere to the Pre-2018 Common Rule as FDA and DHHS regulations have yet to be harmonized. However, adding new consent form elements per the *WSU IRB Informed Consent Policy* will be required, if applicable to your study.
- If your more than minimal risk study was approved before January 21, 2019 and is **not** federally funded or FDA regulated and had received review by the convened board, then the Pre-2018 Common Rule regulations will continue to apply to your study. However, adding new consent form elements per the *WSU IRB Informed Consent Policy* will be required, if applicable to your study.
- If your research received an exemption determination under the Pre-2018 Common Rule prior to January 21, 2019, that exemption still stands unless you make substantive changes to the study design and conduct per the *WSU IRB Exemption Determination Policy*.
- If your minimal risk study was approved via expedited review before or after January 21, 2019 and is **not** federally funded, funded by DOJ or FDA regulated, then the following “hybrid” requirements apply:
  - At continuing review, if previously expedited research now qualifies for an exemption under the Revised Common Rule the IRB Office will grant that exemption with a written exemption letter.
  - At continuing review, previously expedited research will now receive a two-year administrative renewal and after which you will be required to submit an Administrative Renewal Form via the electronic submission system every two years instead of continuing review by the IRB. **However, it is important to understand that you still must submit any amendments and/or reportable event for these studies for expedited reviewed and approval by the IRB. Also, you must add new consent form elements per the WSU IRB Informed Consent Policy, if applicable to your study.**
  - Continuing review by the IRB of minimal risk federally funded research or FDA-regulated research approved before January 21, 2019 will still be required. One or more voting members of the IRB will review the research and if appropriate renew the IRB approval for one year or less.



**There may be some circumstances under which studies conducted under the Pre-2018 Common Rule may be switched to comply with the Revised Common Rule (e.g., multi-site sponsor requirements). When an ongoing federally funded study is switched to the Revised Common Rule, the conversion date must be recorded in the study's electronic records.**