2018 Common Rule and Continuing Review for Minimal Risk Trials

On January 19, 2017, the Health and Human Service (HHS) rules regulating human subjects research known as the Common Rule were revised with the goals of better protecting research subjects and reducing administrative burden. The effective and compliance date of the revised Common Rule is January 21, 2019.

One provision of the revised Common Rule includes the removal of required continuing review for minimal risk trials approved under an expedited review category. Unless otherwise determined by the IRB, these studies will not require annual submission of a continuing review to the DFCI IRB.

What to Expect

For minimal risk new protocol submissions approved on or after January 21, 2019, OHRS will issue a DFCI IRB approval memo indicating that no continuing review is required. The approval memo will not include an expiration date; however, OnCore will indicate an expiration date of **01/01/2020**. 30 days prior to this date, OHRS will send an automated Annual Protocol Renewal (APR) notice which will include a reminder of investigator responsibilities. No action will be required, but this reminder should prompt the study team to close the study via a Study Completion Request if no further activities are taking place. Upon mailing of the APR, OHRS will update the OnCore expiration date to **01/01/20XX** for the following year and will repeat every year until study completion.

Minimal risk studies that were reviewed and approved prior to January 21, 2019 may be transitioned to the revised Common Rule upon approval of the next continuing review. For these studies, continuing review will no longer be required. Study teams will receive a continuing review approval memo which will not include an expiration date; however, OnCore will indicate an expiration date of **01/01/20XX**. Going forward, the same APR process will be applied to these study teams as if they were reviewed and approved after January 21, 2019. Please note, this does not apply to minimal risk trials that have a consent form(s).

Please note that it is at the discretion of the IRB to determine whether or not an annual continuing review will be required for any trial regardless of the minimal risk determination and approval under an expedited category.

References:

45 CFR 46 – 2018 Requirements – Office for Human Research Protections