FAQs on Common Rule Changes

January 18, 2018

New Common Rule - FAQ

On January 17, 2018, the U.S. Department of Health and Human Services announced a delay to the changes to the Common Rule that were scheduled to go into effect on January 19. The Interim Final Rule announced by the agency delays both the effective and compliance dates for the new Common Rule until July 19, 2018, with the option for further delay.

For investigators and study teams, this means that the new continuing review schedule, exempt categories, and other changes in the rule will not go into effect until July 19 at the earliest. The DUHS IRB will continue to review research under the guidelines of the pre-2018 rule until the new rule is implemented. However, the IRB is still requiring that study teams use the updated consent and waiver templates available on the IRB website for new studies. These include the additional elements required under the new rule and will allow for an easier transition when the rule does go into effect.

Please contact your IRB Specialist with any questions.


SEPT 26, 2017 Posting:

Changes to the Common Rule, the primary rule regulating human subjects research, go into effect on January 19, 2018. This FAQ will be updated as new information and guidance becomes available. A number of Duke IRB policies, procedures, and systems will be updated as a result of the changes to the rule. Please note that only studies approved or altered after 1/19/18 will be governed by the new rule; existing studies will need to be amended in order to transition to the new rule.

Investigators will see a number of changes required under the new rule:

- Consent forms will now require a concise summary of study activities, risks, and benefits presented to research participants in advance of the body of the consent document. The IRB will not require re-consent, except when other significant changes are made.
- Additional elements of informed consent are required to be included in consent forms?
these are included in the Duke sample consent template document.

- In requests for waivers to use identifiable data and specimens, the IRB must now find that it would be impracticable to use de-identified data. The waiver request form has been revised accordingly.
- Minimal Risk studies reviewed via the expedited procedure after the new rule goes into effect will no longer require annual continuing review under the new rule, but will require a very brief check-in with the IRB every two years. Remember that the requirement to submit amendments and reportable safety events to the IRB has not changed.
- The Common Rule regulations are separate from FDA regulations. The FDA regulations have NOT changed, so FDA still requires annual continuing review for FDA-regulated studies, even those relatively rare Minimal Risk FDA-regulated studies.

How will the changes to the Common Rule affect NEW submissions to the IRB?

After November 1, 2017, new protocol submissions to the Duke Health IRB will be required to use updated consent and waiver templates that can be found on the IRB website. These are simply updates to existing forms that contain the new required elements of the rule. If a study is approved prior to the 1/19/18 effective date of the new rule, it will remain on the old rule until its next Continuing Renewal. At that point, it will transition to the new rule. If a study is approved on or after 1/19/18, it will automatically be governed by the new rule.

Some studies under the new rule may no longer require annual review. The electronic submission system will prompt you when review is required.

How will the changes to the Common Rule affect my studies at Duke?

Existing Full Board Protocols

Protocols that were reviewed by a full board and are open to enrollment or still in an intervention phase will see the fewest changes under the new Common Rule. At the time of the next renewal or significant amendment affecting the informed consent form that occurs after 1/19/18, you will be requested to update the waiver and consent form to meet the new requirements.

Existing Expedited Protocols

Most studies that were originally expedited by the IRB under the old rule will now be eligible for less frequent review, beginning on 1/19/18. At the time of the next renewal or significant amendment affecting the informed consent form that occurs after 1/19/18, you will be requested to update the waiver and consent form to meet the new requirements. Duke will require an abbreviated renewal (a check-in) every two years in order to keep the study active. This will automatically be prompted by the electronic submission system.

Existing Exempt Protocols
There will be no changes to these protocols. If you have an exempt study that has ended, it is important to close the study with the IRB.

**Additional requirements for federally funded studies**

For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form must be posted to a publicly available Federal website (yet to be specified) after the trial is closed to recruitment and no later than 60 days after the last study visit by any subject.

**What do I need to do now?**

Pay attention to news and announcements from the IRB. Beginning November 1, new submissions must use the new consent and waiver templates.

**How will new information be announced?**

The IRB will host Research Wednesday presentations November 15, 2017 at 1:00; December 13, 2017 at 1:00; and February 14, 2018 at 1:00. This FAQ will be updated if/when guidance is issued from OHRP and when additional policies have changed. We will also share information via the monthly DOCR Newsletter.

**What about Broad Consent?**

The term "Broad Consent" as defined by the new regulations applies to consent for storage and secondary research of identifiable private information or biospecimens. This concept must be implemented on an institutional level and requires tracking of individuals who decline to provide consent. Because there is no guidance from OHRP and because of the implications of tracking individuals who do not provide consent and excluding their data from all future research, Duke is not pursuing broad consent at this time. Investigators can continue to use biospecimens that are coded or to seek waiver of consent for use of biospecimens with identifiers retained consistent with current practices.

**Who can I call if I have questions about a submission or renewal?**

Please call your IRB Specialist. You can find the Specialist assigned to your CRU here by clicking [here](#).

**Where can I find links to the new forms?**

- For tracked and clean versions of the adult and minor DUHS Sample Consent, please click [here](#).
For tracked and clean versions of the database/repository consent template, please click here.

Please click here for examples of the concise summary that must appear at the top of the consent form.

For the revised version of the Waiver or Alteration of Consent and/or HIPAA Authorization, please click here.

Please note other forms (for example, revised Spanish short form consent) will be coming soon.