January 8, 2019

Key Points for New Common Rule: Communication to Research Community

1. The revised Common Rule 45CFR46 will become effective on January 21, 2019.
2. All new studies submitted in iRIS on or after January 21, 2019 must comply with the new regulations.
3. There are four main areas of change:

   - Exemptions
   - Consent Forms
   - Continuing Review for Minimal Risk studies
   - Other/Miscellaneous changes

Exemptions
There are new and revised categories for the IRB to apply when determining a study exempt from IRB review. OHRP (Office for Human Research Protections) has broadened the kinds of research that will be eligible for an exempt determination. As a reminder, per institutional policy, the DUHS IRB (not the Investigator) must make the exemption determination. Studies declared exempt by the IRB do not have to return to the IRB for Continuing Review, and they are given an expiration date of 01/01/2100.

Because Duke has decided not to implement the provisions for ?Broad Consent? institution-wide, Exemption Categories 7 and 8 are not used and are not applicable at Duke.

Click here for new exemption categories.

**Consent Forms**

The revised Common Rule requires that a ?concise summary? of key information appears at the beginning of the consent form:

?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.?

Additionally, the revised Common Rule requires that consent forms contain some new Elements of Consent. The DUHS Sample Consent Template has been revised to reflect the new requirements. The Sample Consent Template, as well as examples of the ?concise summary?, are posted on the IRB web site (Click Here).

The DUHS IRB began requiring a concise summary in new study consent forms in 2018.

**Continuing Review**

The revised Common Rule has new requirements surrounding Continuing Review.

Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances, for new studies submitted in iRIS on or after January 21, 2019:

- Research eligible for Expedited Review (minimal risk studies)
- Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
  - (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
  - (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

For studies meeting the criteria above, a brief IRB ?check-in? will be required every two years. This ?check in? will consist of a brief 1-page summary of events over the last 2 years. Estimated time to complete this summary is about 5 minutes and this will be done within the iRIS system.

At the 2 year check-in, CITI training status will be verified for all key personnel listed on the
study.

PLEASE NOTE: All changes to research and personnel must continue to be reported to the IRB via Amendment, and Closure (Final Progress) Reports continue to be required as usual when studies close.

PLEASE NOTE: All FDA regulated studies will still require annual Continuing Review (or more often than annual, if specified by the IRB).

Transition Provisions for Ongoing Research

For those minimal risk studies that received an Expedited Review upon initial review, and are currently IRB-approved (ongoing research), at the time of your next Continuing Review on or after 1/21/2019, you will complete your Continuing Review as normal, and you will be given the choice whether to transition the study to the new Common Rule regulations, or stay on the old set of regulations. This choice will be made on a study by study basis. There will be a flag or identifier in the iRIS system to denote whether the study is on the new (revised) Common Rule or the old Common Rule.

An important consideration when deciding whether to transition to the new Common Rule is the length of time you expect your study to remain open.

If you choose to have your study remain on the old Common Rule, you do not have to revise your consent form, and your study will continue to receive annual Continuing Review by the IRB.

If you choose to transition your study to the new Common Rule:

- You must modify your consent form to comply with the new regulations
- The IRB will not require re-consent of previously enrolled subjects in this case
- Your study will have a brief ?check-in? with the IRB every two years until study closure
- Posting of consent forms on a federal web site (https://clinicaltrials.gov/) is also a requirement for studies transitioning to the new Common Rule, IF the studies meet certain criteria
- If there is an IRB-approved waiver of informed consent/HIPAA authorization for your study, you must complete the revised Waiver section in the iRIS application

Broad Consent

As is the case with most other large academic Institutions, Duke has decided not to implement the provisions for ?Broad Consent? institution-wide at this time. Consent for future use of data/samples will continue to be addressed on an individual study-by-study basis.

Click Here for OHRP Videos and Resources regarding the new Common Rule.

Consent Form Templates (highlighted):

Below are the consent form templates (Adult and Minor) with the new Common Rule items/elements highlighted in yellow. This will help you easily identify the required elements if transitioning to the new Common Rule. Please note: these new elements have been in the template for several months already.
Attachments

- Consent_Template-Long_Form_ADULT_8-5-2019_highlight.doc
- Consent_Template-Long_Form_MINOR_8-5-2019_highlight.doc