From: Institutional Review Board, BSD [ADM]
Sent: Wednesday, December 27, 2017 3:31 PM
To: ''irbcontacts@lists.uchicago.edu' (irbcontacts@lists.uchicago.edu)'
Cc: #IRB-office-DL; #OCR-office-DL
Subject: January 2018 IRB updates
Attachments: UofCcftemplate Dec 2017.doc

Greetings:

First, we would like to thank you all for our partnership in the protection of human subjects research at the University of Chicago over the past year. The new year will bring changes to the IRB process and we look forward to working with you to implement these changes.

Two significant changes impacting human subjects research oversight go into effect in January:

1) Changes to the Common Rule (DHHS regulations that govern human subjects research); and
2) NIH requirement for Single IRB of Record.

Changes in the Common Rule

The Department of Health and Human Services (DHHS) has issued revisions to the existing Common Rule, the regulations governing human subjects research. These changes will impact the operations of the Institutional Review Board and significantly impact the informed consent process, especially as it relates to the structure and content of consent forms.

Consent Document

Among other new requirements, there is a major change we would like to highlight. As it is recognized that research consent forms are often lengthy and complex, consent forms will now be required to begin with a "concise and focused" presentation of the key information that will likely help someone considering research participation to make a decision about whether or not to participate in a study. As a result of this and other additional requirements, the IRB office has prepared a new consent form template. The new consent form template is attached here and available on the IRB website:
http://bsdirb.bsd.uchicago.edu/forms-guidelines/index.html#consent

We are asking that any new studies submitted for the January 12 deadline use this new template. We ask that the "key information" section of the new consent template be utilized for any consent forms that are over 6 - 7 pages. The requirement for a concise and focused presentation of key information will be mandatory for any federally funded research as of January 19.

Posting of consent forms

The new regulations also require posting of the consent form documents on a publically accessible website within a designated time frame once the study has been closed to enrollment. Guidance from DHHS will be forthcoming as the website has not been identified.

AURA changes

The AURA-IRB form will be modified to reflect requirements in the revised Common Rule. We do not expect these changes to substantially impact researchers submitting to the IRB. Additional communication will follow concerning the content and timeline for updates to AURA-IRB.

Implementation date

These new regulations are scheduled to go into effect for all research **approved on or after January 19, 2018**. As a result, we ask that comments on all currently submitted and still outstanding protocols be addressed prior to this date. If not addressed and approved prior to January 19, existing submissions will be expected to comply with updated requirements.

It should be noted that a request is pending in the Office of Management and Budget to extend the implementation date for the Common Rule changes to 2019. In the event that the implementation date is postponed, additional information will be forthcoming from the IRB office. In the interim, guidance on implementing the new common rule provisions is available on the IRB website at http://bsdirb.bsd.uchicago.edu/ .

Single IRB of Record

In addition, the National Institutes of Health Single IRB Requirement goes into effect on January 25, 2018. This requirement establishes the expectation that a single IRB of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the US. This requirement is effective for all competing grant applications with receipt dates on or after January 25, 2018. The University of Chicago BSD IRB may be able to serve in the role of single IRB in the event that the University of Chicago is the awardee site of the grant. The IRB office has prepared guidance on the use of single IRB in multisite research to assist in this process.

For those who were unable to attend the December 1, 2017 OCR workshop where these changes were discussed, please consider attending the workshop on January 10, 2018 at 12:00 pm in Dora De Lee (L168). In addition, the IRB Directors and Administrators are always available to provide assistance, including at IRB office hours. The office hours schedule and our contact information is online at: http://bsdirb.bsd.uchicago.edu/contact_us.html

Thank you, and we look forward to working with you in 2018.

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