Revised Common Rule: We've Got Your Back

The changes to the Common Rule have significant and far-reaching effects on the regulation of human subject research at UNMC, Nebraska Medicine, UNO, Bellevue Medical Center, and Children's Hospital & Medical Center.

Some of the revisions are more visible to investigators than others, including:

- Changes to consent form format and boilerplate language including the requirement for a "concise and focused presentation of the key information" (an "Executive Summary" no more than two pages).
- Elimination of the requirement for Continuing Review for certain classes of research.

All new research submitted on or after January 21, 2019, and any research submitted before January 21, 2019, but not approved is subject to the new rule.
The IRB has addressed the changes through an extensively revised IRB application compliant with the new rule, and with consent form templates available in RSS. We've worked hard to ensure investigators are covered.

To facilitate the transition to the new rule, applications already started may be continued and completed or may be transferred to the new online application.

**Continuing Review Submission Change:** Studies that require submission of the last-signed consent form with a Continuing Review no longer have to redact (remove) the subject's name, initials or signature.

**RSS Procedure Change:** When a student submits an IRB application, the faculty advisor now must be listed on the application as a faculty advisor AND as a secondary investigator.

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**FAQs: NIH Certificate of Confidentiality**

**What is a Certificate of Confidentiality?**

A Certificate of Confidentiality (CoC) protects the privacy of research participants enrolled in biomedical, behavioral, clinical or other research. With limited exceptions, researchers may not disclose names or any information, documents or biospecimens containing identifiable, sensitive information. The Certificate prohibits disclosure in response to legal demands, such as a subpoena.

**What does it cover?**

Certificates protect names or any information, documents, or biospecimens containing identifiable, sensitive information related to a research participant. This is defined as "covered information" in the policy. In addition, if there is at least a very small risk that information, documents, or biospecimens can be combined with other available data sources to determine the identity of an individual, then they are protected by the CoC. All ongoing or new research funded by the NIH as of December 13, 2016, that is collecting or using identifiable, sensitive information is
automatically issued a CoC.

What do I need to do if I have a CoC?

Researchers with a CoC may not disclose identifiable, sensitive information unless required by other Federal, State, or local laws, such as reporting communicable diseases, if the subject consents, or for the purposes of scientific research that is compliant with human subject research regulations.

Researchers also must ensure that anyone who is conducting research as a subawardee or receives a copy of identifiable sensitive information protected by the policy understand they are also subject to the disclosure restrictions, even if they are not funded directly by NIH.

Who does this effect?

The CoC requirement only affects NIH funded studies that collect identifiable data (or biospecimens). If your study is not NIH funded and you would like to apply for a CoC, consult the UNMC policy for more information.

For more information on the background, policy, or FAQs, visit the NIH CoC Kiosk at https://humansubjects.nih.gov/coc/index

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