Prepping for the New Common Rule Effective 1/19/18

On October 7, 2017, HHS proposed a one-year delay of the general implementation date of the revised Common Rule. The proposed delay is currently under review by the Office of Management and Budget. With the January 19, 2018 deadline looming, however, some IRBs have been preparing for months while others have taken a “wait and see if it’s delayed” approach. The UICOM-P IRB has revised its IRB application forms, consent form template and IRB reviewer worksheets to be compliant with the New Common Rule. The new forms will be published in the IRBNet Forms Library on January 19, 2018 if there is no imposed delay.

What to Expect: New Studies

The new regulations DO NOT impact studies approved prior to January 19, 2018.

For new studies, expect to see:

- IRB Project/Protocol Review Form changes
- Informed consent template revisions
- HRPP Operation Manual updates
- IRB standard operating procedure updates
New studies that are minimal risk will no longer be subject to a yearly Continuing Review.

**What to Expect: Existing Studies**

Open and existing PIRB studies (exempt, expedited and full board) will be “grandfathered,” meaning they will NOT be required to comply with the changes to the Final Rule. These studies will maintain the same consent form, the same expedited or exemption category determinations, and the same Continuing Review cycle until the end of the study.

IRBs can voluntarily choose to transition existing studies to the New Rule on a study-by-study basis if an Institution or a research sponsor requires it.

**A Review of the Other Major Regulation Changes**

**Continuing Review** - No longer required for NEW minimal risk research, including NEW studies that progress to the point of data analysis of identifiable data/biospecimens or obtaining only follow-up clinical data.

**Exemptions** - New categories and clarification of existing categories. Some exemptions may require "limited IRB review" (similar to an expedited review process).

**Informed Consent** - A new "Key Elements" section and a rearrangement of content is designed to facilitate a potential subject's decision to participate or not. The new IRB consent form template will be published in the IRBNet Forms Library for use on January 19, 2018. Studies with consent forms approved prior to January 19, 2018 may remain in the old format.

**Single IRB-of-Record (sIRB)** - IRB oversight for most federally-funded collaborative research projects located in the U.S. will be required to use a single IRB (commercial, academic, or hospital-based) starting January 20, 2020.

**NIH sIRB** - The National Institutes of Health (NIH) is implementing a variation of the Single IRB-of-Record policy beginning January 25, 2018. The NIH sIRB policy may be read here and applies to:

- NIH-sponsored multi-site studies, where the same protocol is used at multiple sites
- Domestic research only

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**UICOM-P CITI Training Requirements Changing Effective 4/1/2018**

The UICOM-P IRB reviewed the current Collaborative Institutional Training Initiative (CITI) requirements for all investigators and authorized study personnel and additional CITI training will be required.

The UICOM-P IRB has adopted the following CITI training requirements effective 4/1/18 for any new
study, continuing review, or addition of authorized study personnel:

1) Biomedical, Social & Behavioral Basic Human Subjects Course (UICOM-P options) or Human Subject Research (HSR) Course (OSF option)
2) Conflict of Interest
3) Good Clinical Practice (ICH Focus) (GCP)
4) Responsible Conduct of Research (RCR)

The courses are available through a CITI affiliation with University of Illinois College of Medicine Peoria (UICOM-P) or OSF HealthCare Systems (OSF).

All investigators and authorized study personnel must meet the UICOM-P continuing education requirement every three (3) years after certification of initial education for as long as they are involved in human subject research. There is no exception to this requirement.

If you have completed all four courses within the last three (3) years through either UICOMP or OSF, no action is required at this time.

Adding CITI Courses

Courses may be added to current CITI affiliations by going to www.citiprogram.org and clicking “Add a Course” below the current courses selected/completed. Next, scroll down to answer the CITI Course Enrollment Questions.

For assistance adding courses to your current CITI registration, please contact Deb Wolf or Wendy Bucklin at 309-680-8630.

Prior to the New Common Rule, if researchers had not obtained study-specific consent, the Old Common Rule allowed only two alternatives for using identifiable data or biospecimens in a research study: 1) obtaining an IRB waiver of consent; or 2) removing personal identifiers so that the research would not involve identifiable private information.

The “New Rule’s” broad consent permits researchers to obtain broad consent for the storage, maintenance, and secondary research use of identifiable biospecimens and data. If broad consent is obtained, any subsequent storage, maintenance, and secondary research uses of the individual’s identifiable biospecimens and data consistent with the broad consent WOULD NOT require additional consent, so long as additional conditions are met, including limited review by an IRB.

Sounds great, right? Unfortunately, the New Common Rule contains an important limitation on the ability of an IRB to waive consent for the future research uses of identifiable data and biospecimens of persons who have been offered a broad consent but HAVE REFUSED to give such consent.

Example: If a researcher asked an individual to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, and the individual “refused to consent,” an IRB CANNOT waive consent for the
storage, maintenance, or secondary research use of that person’s identifiable private information or identifiable biospecimens.

Consent/refusal to consent to broad future use of biospecimens must be documented and tracked. Considering the potential administrative burden to develop and implement a “refusal” tracking system, PIRB will not employ the optional use of broad consent for storage and secondary research at this time.

What does this mean to you?

The PIRB consent form template will not contain the twelve (12) elements required for legally effective broad consent. PIRB will not utilize two of the new exemption categories pertaining to studies involving identifiable private information or identifiable biospecimens that require broad consent.

More Chances to be IRB-Exempt

The New Common Rule establishes new categories of exempt research. Under some of these new categories, exempt research will be required to undergo “limited IRB review.”

Limited IRB review is a type of expedited review to ensure privacy/confidentiality protections are in place with exempt research that involves the collection or use of sensitive, identifiable data. The limited IRB review will be included in the overall exemption review process for exemptions #2 and #3. Exemption #2 now includes studies that collect sensitive identifiable data via surveys, interviews, or observation of public behavior; however, “limited IRB review” is required to ensure adequate protections for privacy and confidentiality.

New Exemption #3 allows benign behavioral interventions in conjunction with data collection involving adult subjects; however, it does not permit deception or concealment unless the subject prospectively agrees to participate in deception research. Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

Examples: Playing an online game, solving puzzles under various noise conditions, or deciding how to allocate a nominal amount of received cash between themselves and someone else.

Exemption #4 is no longer limited to existing data; it can now be applied to secondary research use of identifiable private information and identifiable biospecimens for which consent is not required, as well as identifiable health information regulated under HIPAA, if at least one of the following criteria is met:

- The identifiable private information or identifiable biospecimens are publicly available;
- Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not
contact the subjects, and the investigator will not re-identify subjects; or

- The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b).

**Sponsored or Non-Sponsored Conflict of Interest Form?**

Federal regulations (Public Health Service, National Science Foundation, Food and Drug Administration,) University policies and the Peoria IRB require that investigators disclose significant financial interests related to the research that in any way could bias the design, conduct or implementation, management, and reporting of research data. The regulations further require that there is a mechanism for the investigators to disclose real or potential conflicts and for the development of a management plan that manages, eliminates, or reduces the potential conflict.

The mechanism by which investigators disclose is through the completion of a “sponsored” or “non-sponsored” conflict of interest disclosure form. If your research is supported by an outside organization such as a federal agency, industry or a for-profit pharmaceutical and device company, a “sponsored” conflict of interest disclosure form must be submitted to the IRB. For “sponsored” research, there is usually an agreement, a budget and a set or expectations for reporting back to the sponsor. A sponsored project usually has money in their budget to pay for IRB reviews.

A research project is “non-sponsored,” if the research is funded internally or is unfunded. Non-sponsored research rarely has money available to pay for IRB reviews. If your research is funded internally or is unfunded, a “non-sponsored” conflict of interest disclosure form must be submitted to the IRB for review.

**Upcoming PIRB Meeting Dates**

Thursday, January 11, 2018  
Thursday, February 8, 2018  
Thursday, March 8, 2018  
Thursday, April 12, 2018

*Submission Deadlines are the end of business on the last Thursday of each month*

Meetings are held in Room A100-2 at the University of Illinois College of Medicine Peoria.