

OHRPP Updates

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Today's Topics

- ❖ **Revised Common Rule (update)**
- ❖ **NIH Single IRB Policy (reminder)**
- ❖ **FDA Info Sheet on Payment & Reimbursement**
- ❖ **NIH Certificate of Confidentiality Policy**

Revised Common Rule

- ❖ Released January 19, 2017
- ❖ Effective ~~January 19, 2018~~
- ❖ Uncertainty so far
 - Congressional review
 - Administration review
 - October Delay Proposal
 - January Delay Proposal
 - No clarifying guidance
 - Agency variation

Revised Common Rule

❖ Interim Final Rule issued January 17

- Delayed effective date to July 19
- Suggestion of further delay
- Independent of NIH policies

❖ Possibility that content will be revisited?

❖ Sit tight and stay tuned

- May: expansion of flex measures for non-fed/non-FDA studies?

NIH Single IRB Policy

❖ Reminder

- Policy is now in effect for any grant/contract proposals
- More than one domestic site performing the same protocol
- Proposal must describe plan
 - ❑ OHRPP only released a sample
- Help make sure your PIs are contacting OHRPP early!!
 - ❑ irbreliance@research.ucla.edu

Payment & Reimbursement

- ❖ **FDA Updated Info Sheet on 1/25**
- ❖ **Clarification/Reinforcement**
 - **Payment is NOT a benefit**
 - **Payment raises issues for IRBs**
 - ❑ **Undue influence?**
 - ❑ **Proper description?**
 - **Reasonable travel & lodging is NOT payment**

On a related note...

- ❖ ...since payment is part of recruiting...
 - Be aware of any policies about
 - Communication channels
 - Posting flyers
 - IRB doesn't make these policies
 - IRB can't exempt you from these policies

Certificates of Confidentiality

- ❖ **NIH-funded projects:**
 - human subjects OR
 - very small risk of re-identification
- ❖ **CoCs automatic, retroactive for projects active after Dec 2016**
- ❖ **Responsibilities**
 - Protection from subpoena, etc
 - Extra care in releasing info
 - Notifying recipients, sub-awardees
 - Consent (where applicable)

Certificates of Confidentiality

- ❖ **webIRB deployment tonight**
- ❖ **Announcement tomorrow AM**
 - **Consent language**
 - **What to do with existing studies**
 - **Reminder re responsibilities**
 - **Careful when funding ends**
- ❖ **CoC process for other funders remains the same**

webIRB Change for CoC

3.0 * Is this study conducted or supported by HHS (e.g., the National Institutes of Health, Centers for Control and Prevention, etc.)?

Yes No [Clear](#)

3.1 * Is NIH the HHS agency supporting or conducting the study?

Yes No [Clear](#)

3.2 * Please choose one:

I acknowledge that my study is automatically covered by a Certificate of Confidentiality and I understand the responsibilities associated with that Certificate.

The NIH Certificate of Confidentiality policy does not apply to my study (see guidance at right and explain below)

[Clear](#)

3.2.1

Effective October 1, 2017, NIH automatically grants Certificates of Confidentiality to all human subjects research (and to some use of biospecimens or generation of genomic data whether or not they constitute human subjects research). Please see <https://humansubjects.nih.gov/coc/index> for the policy and other information.

To be exempt from the NIH policy, you must be able to answer no to **all** of the following:

- Does the research involve Human Subjects as defined by 45 CFR Part 46?
- Are you collecting or using biospecimens that are identifiable to an individual as part of the research?
- If collecting or using biospecimens as part of the research, is there a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual?
- Does the research involve the generation of individual level, human genomic data?

Thank you!

❖ For questions:

- **Reliance**
 - ❑ irbreliance@research.ucla.edu
- **North & South General IRBs**
 - ❑ x57122
 - ❑ gcirb@research.ucla.edu
- **Medical IRBs**
 - ❑ x55344
 - ❑ mirb@research.ucla.edu