Georgetown-Howard Universities
Center for Clinical and Translational Science

Recent Regulatory Updates
Common Rule

Kate Cohen, JD, CHRC, CIP

What is the Common Rule?

- Health and Human Services regulations that provides the framework for how the Institutional Review Board reviews human subjects research
- 45 CFR 46
- Regulations have been the same since 1991

Why Change It?

- Intent of the change is to modernize the research regulations to account for the significant development in the types of research being conducted, the settings in which it is conducted, and the technologies utilized

When is It Changing?

WE AREN'T SURE!

- Original compliance date was January 19, 2018
- Rule was postponed on January 17, 2018
- New compliance date is July 19, 2018, but they are already talking about another delay

So What Has Changed?

Definitions

- A few existing definitions have been updated a few new definitions have been updated
- Revisions generally codify the previous interpretation of the terms
- New definitions include “identifiable biospecimen” and “identifiable private information”

Exemptions

- Some existing exemption categories expanded
- New exemptions created
- New limited IRB review requirement for some exemption categories
  - Exempt used to mean the IRB members didn't have to review for approvability- and now they do!

Georgetown-Howard Universities
Center for Clinical and Translational Science

Common Rule Exemption Changes

Pre-2018 Rule		Revised Common Rule
Exempt Category 1	→	Restrictions added to exemption
Exempt Category 2	→	Existing exemption expanded
Exempt Category 3	→	Exemption removed and replaced with a new exempt category 3
Exempt Category 4	→	Existing exemption expanded and new added
Exempt Category 5	→	Existing exemption expanded with changes
Exempt Category 6	→	No Change

NEW!
New Exempt Category 7
New Exempt Category 8

New Limited IRB review

Continuing Review Requirement

- The continuing review requirement for minimal risk studies is ELIMINATED!!

Continuing Review Requirement

- Requirement is eliminated only for minimal risk studies
- IRB can still require continuing review, but must justify it
- Elimination does not apply to FDA regulated studies
- Your institution may still require some type of annual check in

Cooperative Research

- For cooperative research studies (multi-site), single IRB review will be required
- NIH single IRB review already in place- January 25, 2018
- This provision is not required until 2020
- Will apply to all research funded by Common Rule agencies

Informed Consent Changes

- The informed consent document must begin with a concise and focused presentation of key information that is most likely to assist a subject in deciding whether to participate in the study
- What does this mean for you?
  - Your consent document is going to look a little different
  - Your consent process will focus on the information on the first page

Broad Consent

- ***Broad consent may be obtained for the use of identifiable information or identifiable biospecimens*** collected for either research studies other than the proposed research or non research purposes for (1) storage and maintenance for secondary research use, and (2) secondary use
- Required elements of broad consent have been added to the Final Rule

Broad Consent

- Does a researcher have to obtain broad consent if he/she wants to store identifiable information or biospecimens for future research?
  - No! Broad consent is just another option. Researchers can still ask the IRB for a waiver of consent to use previously stored information or specimens or can obtain a study specific consent from individuals
  - Required for new exempt categories 7 and 8

Broad Consent

- Institution is required to track individuals who refuse broad consent because the IRB can not waive the consent requirement for that specific person
- How do we do this?
  - We aren't sure….
  - Most institutions are not implementing this until HHS provides us with more information

So…What Does This Mean For You

Not a lot!

- Continuing Review requirement might impact you and eliminate some paperwork
- Informed consent documents will look a little different
- Single IRB Review

Georgetown-Howard Universities
Center for Clinical and Translational Science

Questions??