Revised Common Rule: Next Steps
Agenda

• To what does this Final Rule apply?
• When does it become effective?
• How is UM preparing?
• New and revised definitions
• Changes to the exempt categories
• Single IRB review for cooperative research
• Revised requirements for informed consent
• Changes to expedited procedures
• Other changes that impact IRB operations
• Questions
On January 19, 2017, the government issued a “final rule”, meant to modernize and strengthen the Federal Policy for the Protection of Human Subjects in Research.

Known as the “Common Rule”, this Policy was originally published in 1991. The stated goal of the revisions is to increase protection of human research participants, while reducing the burden to the research community. The revised Common Rule becomes effective on January 19, 2018.
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.
Common Rule Core

Representatives from key areas within our Human Research Protection Program meet to collectively discuss these changes and how these will impact our research community and work together to come up with new processes. The approach is collaborative and harmonious.

- Dr. John L. Bixby (IO/signatory)
- Dierdre Lacativa – Core Chair
- Johanna Stamates (RCQA)
- Yolanda Davis (RCQA-CTD)
- Helen Miletic (RCQA)
- Helen Blake (Privacy Office)
- Stella Uyeno (Research IT)
- Sorelly Gil (CRORS)
- Barbara Cole (ORA)
- Khemraj Hirani (HSRO)
- Thomas Street (HSRO)
- Joey Casanova (HSRO)
- Kenia Viamonte (HSRO)
NEW AND REVISED DEFINITIONS
.102(b)

**Definition of “Clinical Trial”**

*Clinical Trial* means a research study in which one or more human subjects are **prospectively assigned** to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on **biomedical or behavioral health-related outcomes**.

The consent forms for *clinical trials* will need to be publicly posted. Consent forms for other types of research won’t need to be posted.
.102(e) and (l)

Revised definitions of “Human Subject” and “Research”

• The definition of Human subjects now includes identifiable biospecimens

• Exceptions to definition of Research added for:
  – Scholarly and journalistic activities
  – Public health surveillance activities
  – Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order
  – Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions
New definition of “Written”

Written, or in writing, for purposes of this part, refers to writing on a tangible medium (e.g. paper) or in an electronic format.

The University will review acceptable methods for “e-consent” and further guidance will be provided in the future and communicated accordingly.
CHANGES TO THE EXEMPT CATEGORIES
Revised Exempt Categories

• (1) **Education:** Research conducted in educational settings that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators.

• (2) **Tests, Surveys, Interviews, Observation:** Research that only includes these interactions if at least one of the following criteria is met:
  
  – identity of the human subjects cannot readily be ascertained
  
  – disclosure of responses would not place the subjects at risk of criminal or civil liability or be damaging to subjects’ financial standing or reputation
  
  – identity of the subjects can readily be ascertained but an IRB conducts a limited IRB review and determines there are provisions to protect the privacy of subjects and to maintain the confidentiality of data
.104(d)

New Exempt Categories

- The old category 3 providing lesser protections for elected officials is gone.

- (3) **Benign behavioral interventions:** collection of information from adult subjects through verbal or written responses or audiovisual recording if the subject prospectively agrees and at least one of the following criteria is met:
  - Identity of the subjects cannot readily be ascertained
  - Disclosure of responses would not place the subjects at risk of liability or be damaging to the subjects
  - OR -
  - Identity of the subjects can readily be ascertained but an IRB conducts a **limited IRB review** and determines there are provisions to protect the privacy of subjects and to maintain the confidentiality of data
.104(d)

Revised Exempt Categories (cont)

• (4) **Secondary research**: uses of identifiable private information or identifiable biospecimens for *which consent is not required*, if at least one of the following criteria is met:
  
  – Information or biospecimens are publicly available;
  
  – Identity of the 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;
  
  – Involves only information collection and analysis involving the use of identifiable health information when regulated under HIPAA; or
  
  – Conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities
.104(d)

Unchanged Exempt Categories

• (5) Federal research and demonstration projects: conducted or supported by a Federal department or agency, ... and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs ....

• (6) Taste and food quality evaluation and consumer acceptance studies.
.104(d)

New Exempt Categories (cont)

- (7) **Storage or maintenance of identifiable private information or biospecimens for secondary research:**
  - Limited IRB review is required; *and*
  - Broad consent is required

- (8) **Use of information or biospecimens in secondary research:**
  - Broad consent was obtained;
  - Consent documented or has waiver of documentation;
  - IRB conducts a limited review under 111(a)(7); *and*
  - Does not include returning individual research results to subjects as part of the study plan.

Until the University implements broad consent, these two categories will not be available.
SINGLE IRB REVIEW FOR COOPERATIVE RESEARCH
Single IRB Requirement

- Required for all cooperative research studies.
  - Applies only to U.S. research sites, unless single IRB review is required by law, including tribal law.
  - Funding department/agency can determine that single IRB is not appropriate
    - Rationale must be documented
- IRB is identified by funding department or agency or proposed by the lead institution.
- External (non-institutional) IRBs will be directly subject to OHRP regulatory oversight.

CHANGES TO EXPEDITED PROCEDURES
Changes to Expedited Review

• HHS will evaluate the expedited list every 8 years rather than “as appropriate.” New expedited categories may be available in the future.

• Specific reference is added that the limited IRB review described in the new exempt categories can be expedited.
Changes to Continuing Review

No longer required for:

- Research eligible for expedited review
- Research reviewed by the IRB in accordance with the limited IRB review described in the new exempt categories;
- Research that has progressed to the point that it involves only one or both of the following:
  - (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
  - (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

- One more continuing review cycle may be required for existing studies
CHANGES TO INFORMED CONSENT
.116(a)(5)(i)

“Key information” in Informed Consent

• Begin with... **key information**
• ...in **sufficient detail** relating to the research
• ...to assist a prospective subject... in understanding the **reasons why one might or might not want to participate**....
• ...organized and **presented in a way that facilitates comprehension**.
• ...**does not merely provide lists** of isolated facts

HRP-502x - Template consents will be updated to reflect this requirement. Sponsor consents may still be used provided they satisfy this requirement
.116(b)(9)

New basic element: identifiable private information/biospecimens

- Identifiers might be removed from your information or biospecimens and your information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent."

- OR -

- "Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies."

* Final language is subject to change
.116(c)(7)-(9)  

New additional elements (when appropriate)  

- “Your biospecimens may be used for commercial profit and you (will or will not) share in this commercial profit.”  

- “We will let you know any clinically relevant research results we may find.”  
  - If so, under what conditions  

- “The research might include whole genome sequencing, which is…”  
  - For research involving biospecimens,

* Final language is subject to change
Broad Consent

NOTE: THE UNIVERSITY HAS DETERMINED THAT WE WILL NOT IMMEDIATELY IMPLEMENT BROAD CONSENT.

FURTHER CONSIDERATION FOR POSSIBLE IMPLEMENTATION WILL CONTINUE BEYOND THE EFFECTIVE DATE OF THE REVISED COMMON RULE.
.116(f)

General waiver or alteration of consent

- New criterion for research involving identifiable private information or identifiable biospecimens –
  - the research could not practically be carried out without using such information or biospecimens in an identifiable format.

HRP-410 – IRB checklist for waivers of consent will be updated to reflect this new criterion. Study teams may be asked to justify this in their protocols.
.116(g)

**Waiving consent for screening, recruiting, or determining eligibility (NEW)**

- The IRB may waive consent for screening, recruiting, or determining the eligibility of prospective subjects if:
  - The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative,
  - **OR** -
  - The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.
Posting of Consent Forms (NEW)

- Applies to clinical trials (defined at .102(b)) conducted or supported by a Federal department or agency.
- Informed consent forms must be posted on a Federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject.
  - Posted by the awardee or the Federal department or agency component conducting the trial
- Applicable Federal department or agency may permit or require redactions to the posted information.

Informed consent forms will be posted to [https://www.ClinicalTrials.gov](https://www.ClinicalTrials.gov).
.117

Documentation of Consent

• Recognizes electronic signature

• New waiver option for members of a distinct cultural group or community in which signing forms is not the norm.

• Short form consents must indicate that “the key information was presented first, before other information, if any, was provided”

  • e-Signature implementation under consideration
  • HRP-411 – IRB checklists for waivers of signed consent to be updated
  • HRP-502x – Consent Templates will be updated.
Key Contacts

Clinical Research Operations & Regulatory Support (CRORS) – 305-243-6381

Human Subject Research Office (HSRO) – 305-243-3195

Office of Privacy and Data Security – 305-243-5000

Office of Research Administration (ORA) – 305-284-3871

Research Compliance & Quality Assurance (RCQA) – 305-243-4538

Research Information Technology – 305-243-2314