



Common Rule Update

January 10, 2019

Common Rule - Background

- The Current Common Rule (Current Rule, Pre-2018 Rule, “Old Rule”) was codified in 1991 and 19 Federal Agencies (including HHS) follow this rule.
- The “Revised Common Rule” (RCR, 2018 Rule, New Rule, or Final Rule) goes into effect for research approved on or after January 21, 2019.
 - Note that January 21, 2019 is a National Holiday (MLK Jr. Day), and the University is closed.
 - All of the previous Federal Agencies have signed onto the New Rule, **except for the DOJ**

Common Rule – January 21, 2019

- **Beginning 1/21/2019, IRBs will be responsible for following:**
 - Pre-2018 Rule – For projects approved before 1/21/2019
 - New Rule – For projects approved on or after 1/21/2019
 - Commensurate protections – for unfunded projects
 - FDA Regulations – for projects that involve an investigational drug or device

Migrating Pre-2018 Studies to New Rule

- The regulations allow the IRB to keep studies under the Pre-2018 rule, through the life of the study
- The IRB can decide to move studies to the New Rule
 - If a study is moved to the New Rule, it would need to follow all components of the New Rule, including revised consent requirements and posting consent forms (if applicable)
- **UCLA plans to keep studies approved under the Pre-2018 rule under that rule, except on a case-by-case basis as determined appropriate by the reviewer**

Where do I find guidance?

- Written guidance is so far limited.
- OHRP (HHS) guidance as of 1/10/2019
 - Common Rule Q&As
<https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html>
 - Videos
<https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-videos/index.html>
- **UCLA OHRPP will provide updated guidance and procedures documents over the next few weeks.**

*In the interim, please contact Alison or Mark, or your IRB Administrator,
if you have questions regarding a specific study*

What's Changing?

➤ Lots of considerations for IRB processes

Areas that more directly affect researchers:

- **Definitions**
- **Exempt Research**
- **Continuing Review**
- **Informed Consent**
- **Other changes:**
 - Broad consent
 - Single IRB
 - Required posting of clinical trial consents

New and Revised Definitions

- **Unchanged definitions: Minimal risk, IRB, and IRB approval**
- **New terms defined: Clinical trial, public health authority, written or in writing**
 - *Public health authority is part of description of activities excluded from the definition of research*
- **Minor clarifications made to wording:**
 - Intervention
 - Interaction
 - Private information
 - Identifiable private information

New Definitions

- **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.
 - *Use this definition for determining which studies require posting of the IRB-approved consent form.*
- **Written or in writing:** writing on a tangible medium (e.g., paper) or in an electronic format
 - *Included to clarify that the terms include electronic formats.*
 - *Aligns the Common Rule with US FDA and ICH initiatives*

New Definitions

- **Research: The RCR identifies 4 types of activities as not being ‘research’ as defined in the Rule. So the RCR does not apply to the following types of activities, as they do not meet the regulatory definition of research:**
 - Certain scholarly and journalistic activities
 - Certain public health surveillance activities
 - Collection and analysis of information, specimens, or records, by or for a criminal justice agency for certain criminal justice or investigative purposes, and
 - Certain authorized operational activities for national security purposes
- **Human Subject: The regulatory definition of Human Subject has not been changed in the RCR, but there has been a clarification.**
 - The Pre-2018 Rule referred to “*data*” obtained by an investigator through intervention or interaction ...”
 - The RCR replaces “data” with “*information or biospecimens*” for clarity

Exempt Research

- All but one category was revised; new categories were added.
 - Pre-2018 Rule had 6 exempt categories in section 46.101(b)
 - 2018 Rule includes 8 categories in section 46.104(d)
 - More detailed discussion of Exempt categories is provided in CITI resources provided here: <https://about.citiprogram.org/en/final-rule-resources/#overview>
- **UCLA webIRB Application changes: Categories no longer listed**

Exempt Research – New Category 3

- **Benign Behavioral Interventions in Conjunction with the Collection of Information from Adult Subjects**
 - Brief in duration
 - Harmless, painless, not physically invasive
 - Not likely to have a significant adverse lasting impact on the participants
 - The investigator has no reason to think the participants will find the interventions offensive or embarrassing.

Continuing Review

- **Studies that are minimal risk will no longer need annual continuing review, unless determined by the IRB reviewer.**
- **Greater than minimal risk studies that meet certain milestones will no longer need annual continuing review, unless determined by the reviewer.**
- **UCLA will implement a process of annual reminders of responsibilities for amendments and post approval reports. It will require investigator response to confirm study is active.**

Informed Consent – “Key Information” Summary

Consent forms will need to start with a concise summary of key information - 45.116(a)(5)

Five “factors” (elements) must be included

1. The fact that consent is being sought for research and that participation is voluntary
2. The purposes of the research, expected duration of the prospective subject’s participation, and procedures to be followed in the research
3. The reasonably foreseeable risks or discomforts to the prospective subject
4. The benefits to the prospective subject or others that may reasonably be expected from the research
5. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject

-- Preamble to Final Rule (HHS 2017, 7149-274)

Informed Consent

New required elements of consent (used when appropriate) related to the use of de-identified information, the use of biospecimens, potential for commercial profit and return of clinically-relevant results.

46.116(c)(7) - A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

46.116(c)(8) - A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

46.116(c)(9) - For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Informed Consent – Secondary Research

New required elements of consent for secondary research

46.116(b)(9)(i) -- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility.

46.116(b)(9)(ii) -- A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Other Changes

- **Broad Consent**
 - The Final Rule establishes a framework for “broad consent,” a new type of regulatory consent under the Common Rule for non-exempt storage, maintenance, and research use involving identifiable information and biospecimens.
 - UCLA not currently implementing
- **Clinical Trial Consent Form Posting**
 - Sponsors will be required to post consent forms for clinical trials to a public website/repository identified by OHRP
- **Single IRB of Record Policy**
 - Goes into effect in January 2020
 - Similar to NIH Single IRB policy, already in place

Questions?

Alison Orkin aorkin@research.ucla.edu

Mark Mimnaugh mmimnaugh@research.ucla.edu

UCLA Office of the Human Research Protection Program (OHRPP)