

Human Research News

(Note: This announcement has been superseded by the announcement of January 17, 2018)

Subject: Overview of Revised Common Rule

January 11, 2018

Dear UCLA Research Community,

On January 19, 2018, [a number of changes](#) to the Federal Policy for the Protection of Human Subjects (aka the Common Rule) are scheduled to take effect. The Trump Administration has twice proposed interim rules to delay these changes; the [latest proposal](#) has been in the rulemaking process since January 4.

Federal officials have not said whether an interim rule will be implemented before January 19. If an interim rule is not implemented, the changes will go into effect by default.

In addition, federal agencies have not issued any clarifying guidance and the Food and Drug Administration (FDA) and the Department of Justice have not harmonized their regulations with the Revised Common Rule. If the changes go into effect, they are likely to evolve over the coming months.

Effects on Your Research

Three sets of changes might affect your research starting January 19. OHRPP will make separate announcements this week with more details and tools in these three key areas:

- **Informed Consent:** additional requirements for consent content
- **Continuing Review:** elimination of this requirement for most studies that are approved via the Expedited Review process or for which only certain limited activities remain
- **Exemptions:** clarification to and addition of exemption categories; addition of a “limited IRB review” requirement to certain exemption categories

Studies already approved or certified as exempt before January 19, 2018 remain under the pre-2018 regulations. Neither you nor OHRPP/IRB need to do anything new to these studies at this time. Please continue to submit amendments, continuing reviews, post-approval reports and study closures for these studies as usual.

In the Spring of 2018, OHRPP expects to be able to offer opportunities to convert older studies to the new rules if advantageous to you (for example, elimination of the Continuing Review requirement).

Studies first approved or certified as exempt on or after January 19, 2018 will generally be subject to the Revised Common Rule, but may also be subject to older rules depending on funding and FDA status. Please use the below matrix to classify your new studies. For these studies, consent is the only area that might involve some minor near-term work for PIs and their teams. For a printable version of this matrix, please [click here](#).

Study Characteristics	FDA-Regulated	Not FDA-Regulated
Federal support (except Dept of Justice)	<ul style="list-style-type: none"> • Consent: New Regs • Continuing Review: Old Regs • Exemptions: Old Regs 	<ul style="list-style-type: none"> • Consent: New Regs • Continuing Review: New Regs • Exemptions: New Regs
Dept of Justice support	<ul style="list-style-type: none"> • Consent: Flex • Continuing Review: Old Regs • Exemptions: Old Regs 	
No Federal support	<ul style="list-style-type: none"> • Consent: Flex • Continuing Review: Old Regs • Exemptions: Old Regs 	<ul style="list-style-type: none"> • Consent: Flex • Continuing Review: New Regs • Exemptions: New Regs

***Old Regs** means that pre-2018 regulations continue to apply and override any flexibilities offered by the Revised Common Rule

***New Regs** means that Revised Common Rule requirements apply starting January 19

***Flex** means that the IRB can exercise discretion with the new consent requirements for certain new studies until March 1. This is intended to provide a transition period that minimizes disruption for PIs, study teams and the IRB if a consent form is already written under the old rules. All studies first submitted after March 1 will be required to use new consent templates.

Other Changes

The Revised Common Rule also includes changes to backend IRB operations and recordkeeping, includes changes that do not take effect immediately or that require additional federal guidance for implementation, and newly codifies existing interpretations of the pre-2018 regulations. These other changes do not have any practical effect on your research at this time. OHRPP will make additional announcements about these changes as appropriate.

Key Points

- Federal rule changes are scheduled to take effect January 19 but may be delayed.
- If the changes take effect, studies that are already IRB approved or exempt before January 19 will remain under the old rules.
- Opportunities to convert old studies to the new rules are expected in the Spring.
- Studies that are first IRB approved or exempt on or after January 19 will be governed by a mix of rules determined by funding source and FDA status.
- OHRPP will send separate messages with additional details.

If you have questions after reviewing this and the detailed companion messages, please contact irbregs@research.ucla.edu.

Sincerely,
Kip Kantelo
Director, UCLA OHRPP

This message was originally sent via the Human Research News mailing list. If you would like to subscribe to future announcements, please send an e-mail to: investigators-l+subscribe@lists.ucla.edu. The subject line and body of the e-mail can be blank.