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Dec 3, 2018

Human Research Protection Program

December 19, 2018

To: Investigators and Staff

Re: IRB Regulatory Changes coming January 21, 2019

IRB Regulatory Changes coming January 21, 2019

The Revised Common Rule ^[1] will go into effect on January 21, 2019. This revision of the Federal Policy for the Protection of Human Subjects has been adopted by the U.S. Department of Health and Human Services (HHS) and 15 other Federal Departments and Agencies.

What studies are affected?

The Revised Common Rule only applies to new federally-funded, federally-conducted, and/or VAMC studies approved on or after January 21, 2019. If your study is already approved, or receives IRB approval prior to January 21, the revised policy does not apply.

What are the changes?

Below is a brief outline of the main changes to the Common Rule:

- Continuing Review ? Some new, minimal risk studies will no longer require annual review. The IRB is currently identifying applicable studies and will reach out to researchers who are eligible for this in January.
- Informed Consent ? Several new standard statements are required in the consent form. New consent form templates will be available on the IRB website in January.
- Exemptions ? Several exempt categories will be broadened, and one new category will

be added: Benign behavioral interventions. The IRB application and website guidance will be updated to reflect the changes in January.

What to Expect

In January, the IRB will release an updated application, consent form templates, and FAQs. These materials will be announced via email bulletins and also posted on the website.

Resources

To learn more about the upcoming changes, visit CITI Program's Final Rule Resources [2]. This page offers a comprehensive overview of the revised regulations, but please note that UCSF may implement some of the changes differently than described by CITI.

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Links

[1] <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>

[2] <https://about.citiprogram.org/en/final-rule-resources/>