



University of California
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Common Rule

The Federal Policy for the Protection of Human Research Subjects, also known as the Common Rule ^[1], has been revised for the first time since 1991. The policy changes which include several new requirements for researchers and IRBs go into effect on **January 21, 2019**. This revision of the Common Rule 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?

- New studies that are federally funded or federally conducted will fall under the new rule.
 - New = First-time submissions that have not received IRB approval as of January 21, 2019
 - Federally funded = Receiving funds directly from a federal funding agency (not indirectly)
 - Federally conducted = Study takes place at a federal site, e.g. the VA Medical Center or a National Laboratory

What studies are not affected?

- Studies that are not federally funded or federally conducted
- Studies that have been approved by the IRB **before** January 21, 2019 (regardless of funding source)

What are the main changes?

Review the Town Hall Presentation (see **Resources**, below) for a detailed summary of the changes most likely to impact UCSF researchers.

In brief, the main changes include:

- Continuing Review [2] ? Some new, minimal risk studies will no longer require annual review.
- Informed Consent [3] ? Several new standard statements are required in the consent form. New consent form templates are available on the IRB website here [4].
- Exemptions [5] ? Several exempt categories have been broadened, and one new category has been added: Benign behavioral interventions. The IRB application form and website guidance [5] has been updated accordingly.

Resources:

The guidance throughout the UCSF IRB website has been updated. Additionally, the following resources are available:

- Common Rule FAQ?s [6]
- Town Hall Presentation slides [7] and video [8], ?The New Common Rule? by Laurie Herraiz, HRPP Director. Please note: the slides have been updated with new information about when you should and should not ?convert? to the new IRB Application Form.
- Decision Tool: Does this Study Qualify as Exempt 1, 2, 3, or 4? [9]
- CITI Program's Revised Common Rule Course [10]
- CITI Program?s Final Rule Resources [11]. 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.

Keep checking back for updates. Please contact us [12] with questions.

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Links

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

[2] <https://irb.ucsf.edu/continuing-review>

[3] <https://irb.ucsf.edu/consent-guidelines>

[4] <https://irb.ucsf.edu/consent-and-assent-form-templates>

[5] <https://irb.ucsf.edu/levels-review#exempt>

[6] <https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/faq%20jan%202022%20.pdf>

[7]

<https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/common%20rule%20town%20hall%20slides%20feb%202019.pdf>

[8] <https://lecture.ucsf.edu/ets/Play/726aa4f84172406389289d7a61989f571d>

[9]

<http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/exempt%20category%20decision%20tool%20march%202019.pdf>

[10] <https://about.citiprogram.org/en/course/revised-common-rule-course/>

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

[12] <https://irb.ucsf.edu/contact-us>