The New Common Rule
Changes to the regulations for human subjects research

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Overview

- What’s changing? Why? When?
- Which studies fall under the New Rule?
- What are the main changes?
- How do I comply with the New Rule?
- My new study is not federally funded. How am I affected by the New Rule?
- What tools are available to help me?
What’s Changing?

The Federal Policy for the Protection of Human Subjects that was originally promulgated as a “Common Rule” in 1991
What’s Changing? (cont.)

- **More** research may qualify for Exemptions (exempt from regulations)
- **New Informed Consent** Requirements
- **Continuing Review for Expedited** research may not be required.
- **Note**: UCSF has already implemented some of the changes as best practice in recent years. Overall, the changes will be minor for investigators.

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**Best Practice Alert!**

- This icon means UCSF has used the procedure as a best practice
- **In Use** means the practice is in use currently
- **New!** means the practice is new as a result of the new rule
- **New federally funded/conducted studies only** means the policy change is currently only applied to New, federally funded or conducted studies
Why are things Changing?

- Enhance
- Simplify
- Modernize

This final rule is intended to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.

new federally funded/conducted studies only
When is this happening?

- The compliance date is **January 21, 2019**.
- All new **Federally Funded/Federally Conducted** research approved **on** or **after** January 21, 2019 will be subject to the new rule.
Which Studies fall under the new rule?

- 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 yet
  - Federally conducted = Study takes place at a federal site, e.g. the VA Medical Center or a National Laboratory

- Studies that are not federally funded or federally conducted **will not** be required to comply with the new rule or new Informed Consent requirements until further notice.
Which Studies do not fall under the new rule?

- Studies that are not federally funded and not federally conducted
- Studies that have been approved by the IRB before the new rule compliance date (January 21, 2019)

We will evaluate whether to transition previously approved studies at a later date.
What are the main changes?

(Remember, these changes only apply to new, federally funded or federally conducted to studies)
#1 Exemptions
Main Changes

- New Exemption Categories

- Nothing is changing about the process for submission or review of Exempt applications.

- You are not required to know which category your study may qualify for.

- The application has been programmed to take you through a series of questions that will help determine the most appropriate category.
Exempt Categories (cont.)

Key changes:
1. More categories now allow for research with children and identifiable data
2. Exempt category 3 - allows for low risk, benign behavioral interventions
3. Exempt category 4 - private information and biospecimens no longer have to be in existence prior to the start of the research

new federally funded/conducted studies only
What’s Changing

1. Continuing review is not required for:
   - Research that is eligible for expedited review
   - Studies determined to be Expedited or Exempt after January 21, 2019 will not be required to undergo Continuing Review.
   - Current Expedited Studies will still undergo Continuing Review until further notice.
   - Note: The IRB reserves the right to require continuing review with documentation of the rationale.

2. Grant review not required by IRB

new federally funded/conducted studies only
#3 Informed Consent

What’s Changing

There are several major changes to the general requirements for informed consent in the revised Common Rule.

- The Informed Consent must be presented in sufficient detail that facilitates understanding of why one might or might not want to participate.

- The Informed Consent should not be a list of isolated facts. The goal is to make it easier for subjects to make a decision whether or not to participate.

A brief study summary must be presented at the beginning of the form.

New! new federally funded/conducted studies only
Informed Consent (cont.)

What’s Changing

- **Study Summary** to include: *purpose, the risks, the benefits, and alternatives.*

- **Biospecimens:** requires a notice about whether participants' information or biospecimens collected as part of the current research might be stripped of identifiers and used for other research in the future.

- **Three notices must be added (as applicable):**
  1. Possibility of commercial profit for subjects
  2. Whether clinically relevant research results will be returned to the subjects
  3. Whether research activities will or might include whole genome sequencing.

- **Posting of Consent Forms:** For clinical trials, one IRB-approved version of a consent form that has been used to enroll participants must be posted on a public federal website designated for posting

  Note: There is no current guidance or website designated for posting.

*new federally funded/conducted studies only*
How do I comply with the new rule?

- New version of the IRB application which complies with the New Rule will be available on January 22nd.

- Use the new Informed Consent Form templates on the IRB website.
I already submitted a new study that is federally funded. What do I do?

- You will be contacted by the IRB office regarding the next steps.
- You may be required to convert your current application to the new application which reflects the new common rule changes.
- You will be asked to update an existing Informed Consent or submit a new Informed Consent form for an Exempt study.
- Please be mindful of incoming messages from the IRB office.
- Please contact the IRB office if you have plans to submit a federally funded/conducted study.
Q) My new study is federally funded. When I open the application it tells me there is a new version of the form. What do I do?
A) Convert and answer any new questions.
My new study is not federally funded or conducted, what do I do?

- Your new study is not subject to the Common Rule, but we still ask that you convert to the new application form if you copied your study from a previous application. The new application has some important new questions that the IRB needs to review, regardless of funding source. Be sure to read the instructions in the pop-up window before choosing to convert or not.

- We recommend you use the new consent templates from our website.
I have an approved study. Do I need to convert my application?

- Active studies do not need to convert to the new application form. Click “Cancel conversion” in the pop-up window.

![Image of pop-up window with instructions on converting form version.](image-url)
Will my current studies need to comply?

- There are no changes to currently approved studies.
- Submit Expedited continuing reviews as usual.
Use of Secondary Data v. Broad Consent

**Secondary Data**: data/biospecimens collected by someone else or for some other purpose

- Existing mechanisms for research:
  - Waiver of consent
  - De-identify the data/biospecimens
  - Consent obtained in primary consent form (original study)

**Broad Consent**: Seeking prospective consent for unspecified research on identifiable data/biospecimens

- New mechanism for research: Opt-in consent for future use
- **Caveat**: If patient declines, their data/specimens can never be used for other studies that qualify for a waiver of consent.
- Broad consent is not mandated by the new Rule; it is optional
Broad Consent

- As is the case with nearly all other academic medical centers, UCSF will not be implementing broad consent across the institution at this time.
- Logistical and compliance challenges need to be addressed.
- Seamless IT systems are needed to track between multiple EMRs and repositories/registries.
- Going forward, institutional-level discussion with stakeholders will explore the feasibility for implanting broad consent in compliance with the new regulations.
Summary

- New categories of minimal risk research
  - Some Expedited studies will now be Exempt
  - Some Exempt studies are now considered ‘Not Human Subjects Research’
- New Consent requirements
  - Use the new templates on the IRB website
- Continuing Review not required for some Expedited research
- New iRIS Application

new federally funded/conducted studies only
Tools available to help

- CITI Training ([Citi guidance](#))
- HRPP website
  - [Consent templates](#)
  - Common Rule FAQs
- Federal Office of Human Research Protections
  - [OHRP Common Rule guidance](#)
- UCSF IRB Office ([IRB@ucsf.edu](mailto:IRB@ucsf.edu))