University of California
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# 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?

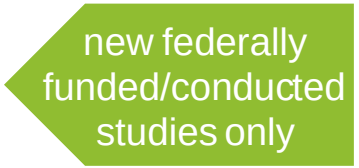
# What's Changing?

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.




| | | | |
|---|---|---|---|
| This icon means UCSF has used the procedure as a best practice | Means the practice is in use currently | New as a result of the new rule | Reminder that the policy change is currently only applied to New, federally funded or conducted studies |

# Why are things Changing?


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

# 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 **<u>will not</u>** 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

# #2 IRB Review

## 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


# #3 Informed Consent

## What's Changing

Best Practice Alert!

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

# Informed Consent (cont.)

## What's Changing

- **Study Summary** to include: *purpose, the risks, the benefits, and alternatives.* New!
- **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.
- **<u>Three notices must be added (as applicable):</u>**
  1. Possibility of commercial profit for subjects ✓
  2. Whether clinically relevant research results will be returned to the subjects New!
  3. Whether research activities will or might include whole genome sequencing. New!
- **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 New!

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

# 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.

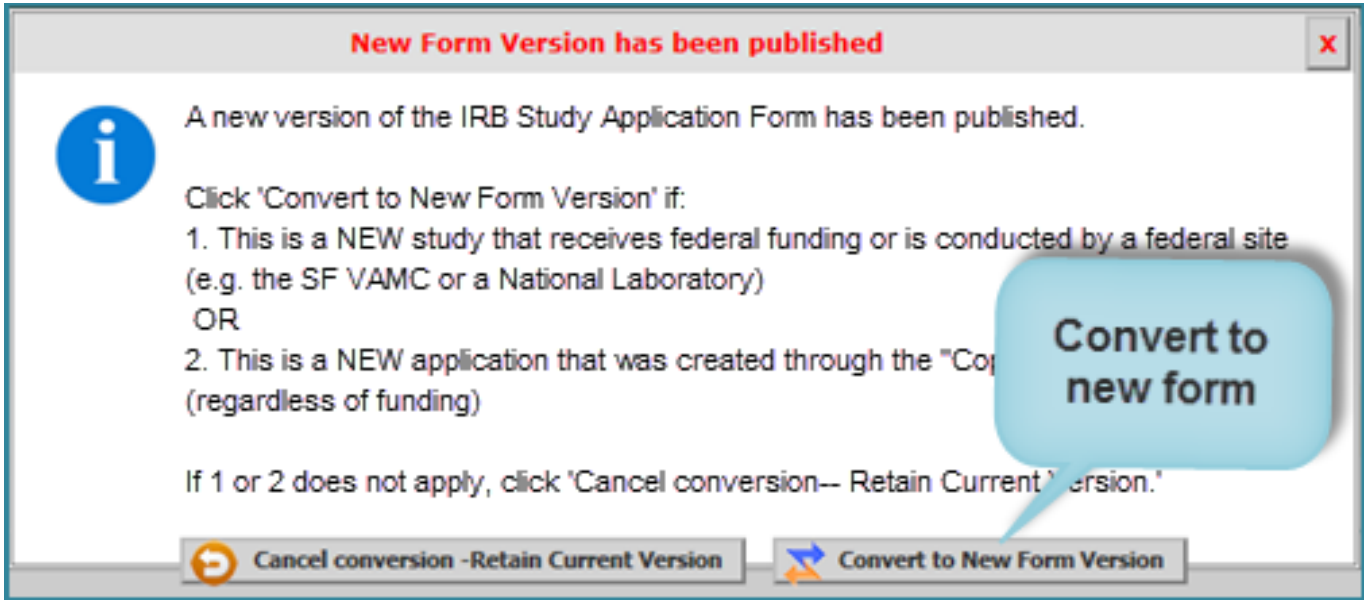
- Use the new Informed Consent Form templates on the IRB website.

# 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.




new federally funded/conducted studies only

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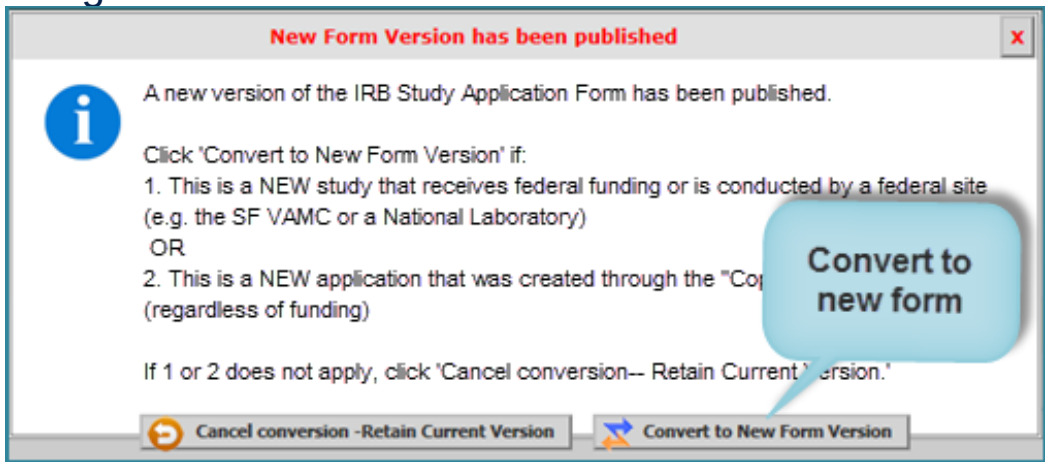
# My new study is not federally funded or conducted, what do I do?

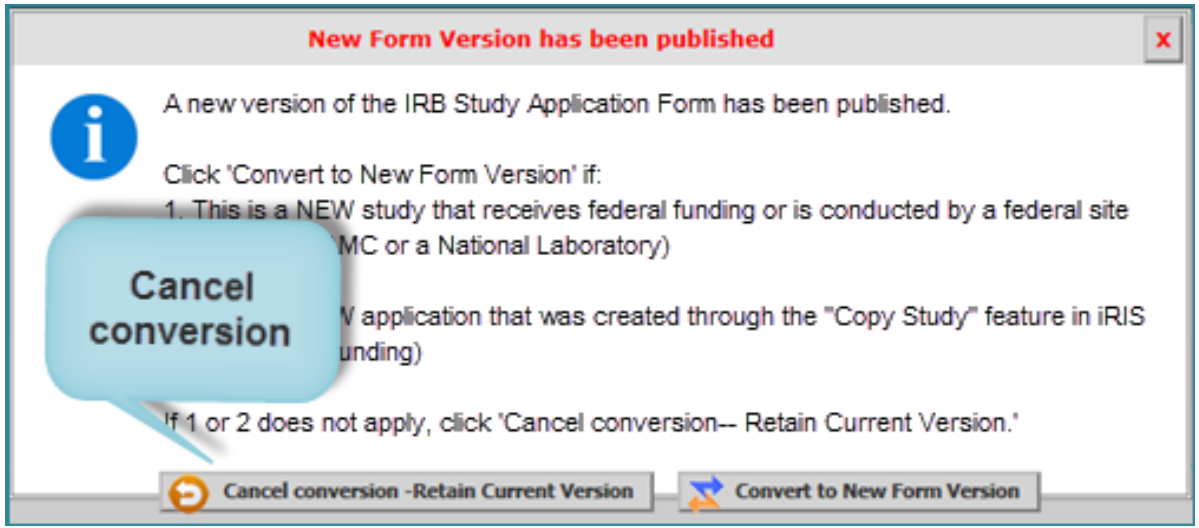
- Your new study is not subject to the Common Rule, but we still ask that you convert to the new application form if you copied your study from a previous application. The new application has some important new questions that the IRB needs to review, regardless of funding source. Be sure to read the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



# 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

# 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)