

## Revised Common Rule

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## 1. What studies are affected by the revised Common 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 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

## 2. What studies are not affected by the revised Common Rule?

- Studies that are not federally funded or federally conducted
- Studies that have been approved by the IRB before January 21, 2019

## 3. I have a study that has current IRB approval. What do I need to know about the revised Common Rule?

The policy changes do not affect you at this time. Your study is grandfathered under the earlier version of the Common Rule (UCSF is now referring to this as the **Former Common Rule**) and/or UCSF IRB's earlier policies.

## 4. I submitted a new application (federally funded or federally conducted) to the UCSF IRB and do not have IRB approval yet. What should I expect?

- 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.

We appreciate your patience through this process.

## 5. How do I know if I'm on the "old" vs. "new" application form?

Open your application and go to the "Initial Screening Questions" section. If the date on that page is January 2019, you are on the new application form.

## 6. I'm submitting a new, federally funded (or federally conducted) study. How do I comply with the revised Common Rule?

- Use the new Informed Consent Form [templates](#).
- Use the new version of the IRB application which complies with the New Rule. If you start your new application before 1/22/19, you will need to convert to the new application form (view slide #17 of

the IRB's Town Hall presentation for instructions on how to convert to the new form). If you start your new application on/after 1/22/19, you will automatically be on the new form.

- Please contact the IRB office if you have plans to submit a federally funded/conducted study. We can help ensure that you are using the correct forms.

### **7. I have an approved federally-funded study. Do I need to update my application and consent form when I submit a continuing review?**

No. We are currently only applying the new policy requirements to new (initial review) studies that are federally funded/conducted.

### **8. What are the main changes in the revised Common Rule?**

Most changes “relax” the regulatory requirements for research. At a very high-level, the changes include:

- More types of research qualify as exempt research.
- Reframing of what it means for a human subject to be “vulnerable”.
- Eliminating continuing review for some studies.
- New statements required in consent forms.
- The IRB no longer has to review federal-funding proposals (i.e. grants) alongside study submissions.
- Other changes that affect IRB operations.

### **9. Does the revised Common Rule change what is considered “research”?**

No. Research is still defined as: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. 45 CFR 46.102(d) (Former Common Rule) or 45 CFR 46.102(l).

However, the revised Common Rule explicitly provides examples of activities that are “not research” (all of which UCSF previously assessed as “not research”):

- (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
- (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

## 10. Does the revised Common Rule change the definition of “human subject”?

Yes.

Former Common Rule 45 CFR 46.102(f)	Redline Changes	Revised Common Rule 45 CFR 46.102(e)
Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:	Human subject means a living individual about whom an investigator (whether professional or student) conducting research <del>obtains:</del>	(1) Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
(1) Data through intervention or interaction with the individual, or	<u>Obtains <del>data</del> information or biospecimens</u> through intervention or interaction with the individual, <u>and uses, studies, or analyzes the information or biospecimens;</u> or	(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
(2) Identifiable private information.	<u>Obtains, uses, studies, analyzes, or generates</u> identifiable private information <u>or identifiable biospecimens.</u>	(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

## 11. Does the revised Common Rule change what is considered “exempt” research?

Yes. The changes in the exempt regulations are fairly extensive. The changes generally expand the categories of research that qualify as exempt research. A brief summary is outlined below. But additional information can be found in subsequent FAQs and supporting documents.

Former Common Rule 45 CFR 46.101(b)	Revised Common Rule 45 CFR 46.104(d)
Category 1:  Research conducted in established or commonly accepted educational settings, involving normal educational practices.	Category 1: <b><i>(Comparable to Former Category 1)</i></b>  Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.
Category 2:  Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.	Category 2: <b><i>(Comparable to Former Category 2)</i></b>  Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior.
Category 3:	Category 3: <b><i>(New Category)</i></b>

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2).	Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection.
Category 4:  Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.	Category 4: <b>(Comparable to Former Category 4)</b>  Secondary research for which consent is not required.

## 12. How has Exempt Category 1 changed under the revised Common Rule?

In brief, Category 1 clarifies that such research should not adversely impact the students' opportunity to learn the required educational content or the assessment of the educators providing the instruction.

Former Common Rule 45 CFR 46.101(b)(1)	Redline Changes	Revised Common Rule 45 CFR 46.102(e)(1)
Research conducted in established or commonly accepted educational settings,	Research, conducted in established or commonly accepted educational settings,	Research, conducted in established or commonly accepted educational settings,
involving normal educational practices,	<del>Involving</del> <u>that specifically involves</u> normal educational practices...	that specifically involves normal educational practices...
	<u>...that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.</u>	...that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.
such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.	<u>This includes most</u> research on regular and special education instructional strategies, <del>or</del> <u>and</u> research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.	This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

### 13. How has Exempt Category 2 changed under the revised Common Rule?

In brief, Category 2 has clarified:

- Research can include **interactions** (but still not **interventions**); and
- If research does not meet either subsection (i) or (ii) (i.e. readily identifiable and risk of harm of breach of confidentiality), it can still qualify for Exempt Category 2 if it gets **Limited IRB Review** and approval.

Former Common Rule 45 CFR 46.102(f)	Redline Changes	Revised Common Rule 45 CFR 46.102(e)
(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:	Research <u>that only includes interactions</u> involving <del>the use of</del> educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior <del>unless</del> <u>(including visual or auditory recording) if at least one of the following criteria is met:</u>	(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and	<u>The</u> information obtained is recorded <u>by the investigator</u> in such a manner that <u>the identity of the</u> human subjects <del>cannot readily be identified</del> <u>ascertained</u> , directly or through identifiers linked to the subjects;	(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.	Any disclosure of the human subjects' responses outside the research <del>could</del> <u>would not</u> reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, <u>educational advancement</u> , or reputation; <u>or</u>	(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
	<u>The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).</u>	(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

#### 14. What is Exempt Category 3 under the revised Common Rule?

This is a new category of exempt research. In brief:

- Category 3 permits **interventions** (specifically, benign behavioral interventions).
- If Category 3 research involves deception, there must be a mechanism to inform, and get approval from, the human subject.
- If the information is recorded in a way that the identity of the human subjects can readily be ascertained, it can still qualify for Exempt Category 3 if it gets Limited IRB Review and approval.

*Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:*

*(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;*

*(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or*

*(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).*

*(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.*

*(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.*

## 15. How has Exempt Category 4 changed under the revised Common Rule?

In brief, Category 4:

- Expands so that, rather than limit use to existing data and specimens, it simply requires that the data and specimens were collected for a different purpose. This means that the data and specimens do not have to “exist” at the time you submit an exempt application for initial review.
- Now includes research for permitted uses under HIPAA (see below).
- Now includes research that is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities.

Former Common Rule 45 CFR 46.101(b)(4)	Redline Changes	Revised Common Rule 45 CFR 46.104(d)(4)
Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if...	<p><del>Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if...</del></p> <p><u>Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:</u></p>	Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
...these sources are publicly available...	<p><del>These sources</del> <u>The identifiable private information or identifiable biospecimens</u> are publicly available;</p>	(i) The identifiable private information or identifiable biospecimens are publicly available;
...or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.	<p><del>Or if the</del> Information, <u>which may include information about biospecimens,</u> is recorded by the investigator in such a manner that <u>the identity of the human</u> subjects cannot <del>readily be identified</del> <u>ascertained</u> directly or through identifiers linked to the subjects, <u>the investigator does not contact the subjects, and the investigator will not re-identify subjects;</u></p>	(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
	<p><u>The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public</u></p>	(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501



	<a href="#">health activities and purposes” as described under 45 CFR 164.512(b); or</a>	or for “public health activities and purposes” as described under 45 CFR 164.512(b); or
	<a href="#">The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.</a>	(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

## 16. What is “Limited IRB Review”?

**Limited IRB review** is a new type of IRB review permitted in the revised Common Rule for specific types of exempt research (also specified in the revised Common Rule). When exempt research requires **limited IRB review**, the New Application will prompt the investigator to answer additional question(s). In addition to a qualified reviewer evaluating the exempt research, the IRB will make the determinations required by 45 CFR 46.111(a)(7):

*When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.*

The IRB will conduct this review through the expedited review process. 45 CFR 46.110(b)(1)(iii) (Common Rule). This limited IRB review generally does not require continuing review. 45 CFR 46.109(f)(1)(ii) (Common Rule).

## 17. Are there changes to Continuing Review requirements for new federally funded and federally conducted studies?

Yes! The most important change is that research eligible for expedited review (as described in the Federal Register) is not required to undergo continuing review unless the IRB determines otherwise.

Therefore, expedited review studies will no longer have an expiration date and no longer undergo continuing review (unless required by the IRB).

#### **18. If I don't need to submit continuing reviews anymore, do I need to submit anything to the IRB?**

Even if you do not need to submit continuing reviews, you still need to submit the following to the IRB:

- Modification forms
- Personnel changes
- Protocol violations, adverse events, and reports
- Closeout reports

#### **19. I have an approved expedited study with federal funding. Do I still need to submit continuing reviews?**

For now, you still need to submit continuing reviews unless the IRB has specifically told you otherwise. Once we settle into the new regulations, we may allow existing studies to convert to the new policy, and we will make an announcement when that happens.

#### **20. Does the revised Common Rule change the informed consent requirements for federally funded or federally conducted studies?**

Yes. The consent form templates have been updated to include statements for the following newly required information:

- Study Summary at the beginning of the form
- Future use of de-identified data and biospecimens
- Return of clinically relevant results (if applicable)
- Sharing of commercial profits (if applicable)
- Whole genome sequencing (if applicable)

#### **21. Does the revised Common Rule change the criteria for waiving documentation of informed consent?**

The **revised Common Rule** has one additional category for which an IRB can waive documentation of informed consent:

*If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the IRB must find that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. 45 CFR 46.117(c)(1)(iii).*

For FDA-regulated research, the FDA regulations do not have similar provisions. As such, investigators may need to request a waiver of documentation of consent in accordance with 21 CFR 56.109(c).

**22. What is broad consent (as defined by the Common Rule) and why isn't UCSF adopting it at this time?**

Broad consent is one option for the storage, maintenance, and secondary research on identifiable data and biospecimens. As is the case with nearly all other academic medical centers, UCSF will not be implementing broad consent across the institution at this time for the following reasons:

- OHRP has not issued any guidance on the topic.
- Logistical and compliance challenges need to be addressed. If a subject opts-out, no investigator or IRB can subsequently waive the subject's consent for any future study.
- Seamless IT systems are needed to track between multiple EMRs and repositories/registries.

There continue to be multiple options available to conduct secondary research:

- Waiver of consent
- De-identify the data/biospecimens
- Consent obtained in primary consent form (original study)

**23. Has the revised Common Rule changed the requirements for including "vulnerable populations" in research?**

Yes, but the effects on investigators and research is nominal. It is important that investigators understand the change in semantics:

The vulnerability of human subjects is always contextual – depending on the study, research team, and recruitment population. To that end, the UCSF IRB and HRPP will continue to exercise discretion in ensuring that human subjects that may be vulnerable are appropriately enrolled and protected.

The regulations identify populations that are inherently considered vulnerable. Under the Former Common Rule, they were referred to as **vulnerable populations** and the revised **Common Rule** uses the term **categories of subjects who are vulnerable to coercion or undue influence**. 45 CFR 46.111(a)(3) (Common Rule).

Below are the categories of human subjects that the regulations consider "vulnerable":

Category	Former Common Rule	Revised Common Rule
Children	Vulnerable	Vulnerable
Prisoners	Vulnerable	Vulnerable
Pregnant women	Vulnerable	
Mentally disabled persons	Vulnerable	
Economically disadvantaged	Vulnerable	Vulnerable
Educationally disadvantaged	Vulnerable	Vulnerable
Individuals with impaired decision making capacity		Vulnerable