



UC BERKELEY HUMAN RESEARCH NEWS



FALL
2018

VOLUME 5
ISSUE 2

INSIDE THIS ISSUE

- 1 Letter from the Chairs
- 2 Transitions to the Final Rule
- 3 Exempt Categories
- 4 Exempt Categories (cont.)
- 5 Research Definition & Consent Waiver Criteria Updates
- 6 Clinical Trials

Fall 2018 Newsletter

Dear Members of the UCB Human Research Community,

At long last, the much-discussed revisions to the Common Rule, also known as “the Final Rule” or “the 2018 Requirements,” will finally be implemented... in 2019! (On January 21, to be exact.) Per the U.S. Department of Health and Human Services, “This final rule strengthens protections for people who volunteer to participate in research, while ensuring that the oversight system does not add inappropriate administrative burdens, particularly to low-risk research.” If you’re interested in the full story of how things came about, you can [read all about it](#) on the HHS.gov website.

To use a traffic analogy, it may feel like a new lane has opened on the ‘IRB freeway.’ Some travelers may find things moving along more quickly and smoothly; many will continue in the same lane without any noticeable difference; and some will encounter a few new tolls or restrictions. It is hoped that the overall effect will be one of reduced burden and increased efficiency, without any loss in protection of research participants.

Things moving faster

- A [clarified definition](#) of “research” excludes certain scholarly and journalistic activities. (See inside the newsletter for more details.) Projects of this nature will no longer require submission to OPHS/CPHS for review and approval/exemption.
- (Dis-) Continuing Review. The next renewal may be the last! When protocols are transitioned to comply with the 2018 Requirements (at the time of renewal or through an amendment), they may be eligible for a 10 year approval period—provided they meet [certain criteria](#).
- The requirement for the IRB to conduct a grant-protocol comparison will be eliminated as well. [In OHRP’s words](#), “Experience suggests that review and approval of the application or proposal is not a productive use of IRB time.” We couldn’t agree more.

Speed bumps

- Compliance with the 2018 Requirements involves some modifications to informed consent, to better assist prospective subjects in making their decision to participate in research or not. These requirements affect the content, organization, and presentation of information in the consent form, as well as the basic and additional elements of consent (in certain circumstances). See also the section on Clinical Trials and consent form posting requirements, inside this newsletter.

Cruise control

- While revisions to the Common Rule impact almost every exemption category, the net effect may not be very noticeable to members of our research community. For the most part, the categories have been clarified and expanded. Under the flexibility of UC Berkeley’s Federalwide Assurance (FWA), we established “Exempt Category 7” about four years ago. This category permits certain non-federally funded, minimal risk studies involving tasks and non-physically invasive interventions to be reviewed at the exempt level. Under the 2018

cphs.berkeley.edu
ophs@berkeley.edu
510-642-7461

FALL
2018

VOLUME 5
ISSUE 2

INSIDE THIS ISSUE

- 1 Letter from the Chairs
- 2 Transitions to the Final Rule
- 3 Exempt Categories
- 4 Exempt Categories (cont.)
- 5 Research Definition & Consent Waiver Criteria Updates
- 6 Clinical Trials

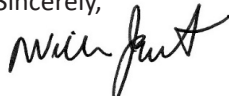
(Letter from the Chairs continued)

Requirements, some of these activities will be eligible for review under federal exemption category #3. When exempt protocols are submitted to OPHS/CPHS for amendment, they may be re-categorized for compliance with the 2018 Requirements. We will continue to utilize our flexibility for non-federally funded studies that are otherwise not permitted under the “new” federal exemption categories, under what will now be called “Exempt Category 70.”

- FDA Regulations. The 2018 Requirements apply to HHS-regulated (Common Rule) agencies only. The FDA regulations have not changed, although FDA plans to issue a notice of proposed rulemaking to harmonize its regulations with the Common Rule. Revised consent forms under the 2018 Requirements are consistent with FDA regulations, but continuing review will still be required at intervals appropriate to the degree of risk, but not less than once per year.

In the following pages you’ll find more information about the transition to 2018 Requirements and resources for assistance and guidance.

Sincerely,



William Jagust, M.D.
Chair, CPHS-1



Jane Mauldon, Ph.D.
Chair, CPHS-2



Transitions to the 2018 Requirements/Final Rule: What do I need to do, and when?

Possibly Nothing. Ongoing studies, both exempt and non-exempt, may continue according to their approved procedures under the pre-2018 Common Rule requirements. No action is needed unless/until an amendment is requested or the study comes up for renewal.

Update Your Consent Forms. Compliance with the Final Rule will require some modifications to informed consent. Key information about the study (such as the purpose, the risks, the benefits, and alternatives) must be provided at the beginning of the consent form, and it must be presented in sufficient detail and organized in a way that facilitates understanding. The goal is to help participants think about why they might or might not want to participate in a study and make a decision that reflects their interests.

In addition, a notice is required 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. Consent forms will need to say either that this will or will not happen.

See the templates and sample consent forms for Federally Regulated Research on [this page](#). We suggest you use these templates even if your study is not federally funded.

When? Now. Compliance with the Final Rule will be required as of January 21, 2019 for all amendments and renewals as they come in. Note that the updates to the consent form are *not inconsistent* with the pre-2018 requirements, so we recommend that you go ahead and make the changes for amendments and renewals submitted before the compliance date.

Exempt amendments will be reviewed by OPHS analysts and may be reassigned to a different exempt category when applicable. Note that consent documents for exempt studies should be

FALL
2018

VOLUME 5
ISSUE 2

INSIDE THIS ISSUE

- 1 Letter from the Chairs
- 2 Transitions to the Final Rule
- 3 Exempt Categories
- 4 Exempt Categories (cont.)
- 5 Research Definition & Consent Waiver Criteria Updates
- 6 Clinical Trials

(Transitions continued)

updated to comply with the requirements described above, but the documents themselves will not be reviewed.

What about new submissions? For now, proceed as usual with the current eProtocol Exempt and Non-exempt application forms, as these are still in effect until January 21. Make sure that your consent forms comply with the 2018 Requirements, in case approval is not received before then. The Exempt application will be updated in eProtocol with the new categories on Jan. 21. Applications that are pending when the Final Rule goes into effect on January 21, 2019, will automatically transition to the new forms (and new regulations).

What if I'm just getting started? When preparing to submit a new application, consider whether the proposed study meets the revised definition of research, and whether it could fit within the revised/expanded exempt categories. (See following pages for additional information.) If an expedited application is submitted on or after December 17, 2018 and would qualify for exempt review under the new regulations, investigators may be asked to reapply on an exempt form. Applications that are pending when the Final Rule goes into effect on January 21, 2019, will automatically transition to the new forms (and new regulations).



Abridged Summary of Changes to the Federal Exemption Categories

Category #1: Educational Practices

This category applies to research in established or commonly accepted educational settings that involves certain normal educational practices. The 2018 revisions to the Common Rule have added a new restriction to the applicability of Exemption 1: the research must also not be likely to adversely impact the student's opportunity to learn required educational content or the assessment of educators who provide the instruction.

Category #2: Educational Tests (Cognitive, Diagnostic, Aptitude, Achievement), Survey Procedures, Interview Procedures, or Observation of Public Behavior

There have been three primary changes to Exemption 2 in the revised Common Rule. First, the word "only" has been added to clarify that Exemption 2 applies to research that "only includes interactions" involving educational tests, surveys, interviews, and observation of public behavior. Exemption 2 (still) is not applicable to research involving interventions.

Second, the applicability criteria have been expanded to require that the disclosure of the subjects' responses outside the research would not reasonably be damaging to the subjects' "educational advancement."

The third main change to this category is that it has been expanded to cover collection of identifiable information (even if sensitive), provided that an IRB determines through limited review that, when appropriate, there are adequate privacy and confidentiality protections in the study.

Category #3: Benign Behavioral Interventions in Conjunction with the Collection of Information

With the expansion of Exemption 2 (see above), the pre-2018 Exemption 3 has been replaced by a new exemption applicable to certain research involving benign behavioral interventions* in conjunction with the collection of information through verbal or written responses or audiovisual recording. At least one of the following criteria must be met:

- a. The information obtained is recorded in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to subjects; or

FALL
2018

VOLUME 5
ISSUE 2

INSIDE THIS ISSUE

- 1 Letter from the Chairs
- 2 Transitions to the Final Rule
- 3 Exempt Categories
- 4 Exempt Categories (cont.)
- 5 Research Definition & Consent Waiver Criteria Updates
- 6 Clinical Trials

(Exemption Category #3 continued)

b. Any disclosure of the human subjects’ responses outside the research would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or

c. Data collection is not anonymous and potentially sensitive or harmful information is collected from subjects. Studies only qualify for this exemption category if CPHS conducts a limited IRB review and determines that there are adequate provisions for protecting subject privacy and maintaining confidentiality.

The new Exemption 3 applies to behavioral interventions only. It is not applicable to biomedical research. Additionally, it applies only to research with adults; it is not applicable to research with children.

**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.*

Category #4: Secondary Use of Data

Exemption 4 applies to the secondary research use of identifiable private information or identifiable biospecimens (i) if these sources are publicly available; or (ii) 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, and the investigator does not contact or re-identify subjects. One change in the revised Common Rule is that the private information and biospecimens no longer have to be in existence prior to the start of the research. Under the revised rule, for example, a research study that proposes to analyze samples or information that will be collected for clinical purposes in the future could qualify for this exemption if it meets at least one of the applicability provisions.

Another change is that if an investigator records information about individuals in a nonidentifiable manner, the investigator must not attempt to re-identify or contact the research subjects.

Category #5: Public Benefit or Service Programs (Federal Department or Agency)

Exemption 5 applies to research that is designed to study, evaluate, improve, or otherwise examine public benefit or public service programs, if the research is conducted by a federal department or agency. This has been expanded to include research that is also supported by a federal department or agency (for example, through a grant of funding). There is also a new requirement for the federal entity conducting or sponsoring the research to publish a publicly available list of the projects that are covered by this exemption before the research begins.

This category is rarely used for research at UC Berkeley. Research and demonstration projects in general (e.g., state or city funded public service programs) do not fit under this exempt category.

Category #6: Taste and Food Quality Evaluation and Consumer Acceptance Studies

No changes!

UC Berkeley Category #70

The revised Common Rule includes eight categories of research activities that may be exempt. CPHS has determined that federal categories 7 and 8 are more onerous than beneficial and, therefore, will not be available for use at UC Berkeley. In keeping with CPHS’ efforts to minimize research compliance burden, an additional, UCB-defined category of exempt research activities is available as permitted by UCB’s Federalwide Assurance: category #70 (formerly #7).



FALL
2018

VOLUME 5
ISSUE 2

INSIDE THIS ISSUE

- 1 Letter from the Chairs
- 2 Transitions to the Final Rule
- 3 Exempt Categories
- 4 Exempt Categories (cont.)
- 5 Research Definition & Consent Waiver Criteria Updates
- 6 Clinical Trials

But Wait ... There's More!

Activities Not Considered Research

While the federal definition of “research” has not changed under the 2018 Requirements, a provision has been added to clarify that certain activities are not considered research for purposes of regulatory oversight. These activities include:

- 1) Certain scholarly and journalistic activities,
- 2) Certain public health surveillance activities,
- 3) Collection and analysis of information, specimens, or records, by or for a criminal justice agency for certain criminal justice or investigative purposes, and
- 4) Certain authorized operational activities for national security purposes.

Below is the definition of research at 45 CFR 46.102(l), along with the new Final Rule text pertaining to exclusion of scholarly and journalistic activities:

*(l) Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, **the following activities are deemed not to be 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.*

As noted in [OHRP guidance](#), this category of activities “concerns scholarly and journalistic activities often conducted in various fields that **focus directly on the specific individuals about whom information is collected and used**, without extending that information to draw generalizations about other individuals or groups. ... The objective of the activities in this category is to provide an accurate and evidence-based portrayal of the individuals involved, and **not to develop generalizable knowledge.**”

Projects consisting only of these activities should not be submitted to OPHS/CPHS for review. If you are not certain whether your project requires review, contact OPHS staff for guidance.

(Please refer to 45 CFR 46.102(l) of the [revised Common Rule](#) for the full description of the excluded categories of activities.)



Informed Consent Waiver Criteria Updates

New Waiver Criterion for Informed Consent

There is a change regarding the waiver and alteration of informed consent in the revised Common Rule. There is one new waiver criterion, which applies to research with identifiable private information or identifiable biospecimens. This new criterion is that *the IRB must determine that the research could not practicably be carried out without using the information or biospecimens **in an identifiable form.*** The purpose of this additional criterion is that if the research could

FALL
2018

VOLUME 5
ISSUE 2

INSIDE THIS ISSUE

- 1 Letter from the Chairs
- 2 Transitions to the Final Rule
- 3 Exempt Categories
- 4 Exempt Categories (cont.)
- 5 Research Definition & Consent Waiver Criteria Updates
- 6 Clinical Trials

(Waiver Criteria Updates continued)

be done using non-identifiable information, then that is what should be done. In these cases, researchers shouldn't be using identifiable information because it increases the risk of breaches of privacy or confidentiality.

Expansion of Waiver of Documented Consent Criteria

There is a change regarding documentation of consent, which refers to obtaining someone's signature before they can participate in a study. This change is an expansion of the waiver of the signature requirement. In addition to waiver criteria that existed in the pre-2018 Requirements, an IRB may waive the requirement for a signed informed consent form *if the subjects are members of a **distinct cultural group or community** in which signing forms is not the norm*, the research involves no more than **minimal risk**, and there is an **alternative method for documenting** that consent was obtained. Note that there are other requirements in the pre-2018 Common Rule about when the signature requirement can be waived, and those continue in the revised Common Rule.



Clinical Trials

New Consent Form Posting Requirement

As you may recall, the NIH recently modified their definition of a "clinical trial." (See our [Fall 2017 Newsletter](#) for more details.) The new definition states that a clinical trial is:

"A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

The Final Rule (45 CFR 46.116(h)) includes consent form posting requirements for clinical trials conducted or supported by any Federal department or agency (not just NIH). For such studies, 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 such consent forms. The form must be posted after recruitment closes, and no later than 60 days after the last study visit.

Which websites can be used? From HHS: "At this time, two publicly available federal websites that will satisfy the consent form posting requirement, as required by the revised Common Rule, have been identified: ClinicalTrials.gov and a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021). HHS and other Common Rule departments and agencies are developing instructions and other materials providing more information to the regulated community about this posting requirement."



UC BERKELEY
HUMAN RESEARCH
NEWS STAFF

Managing Editor:
Sarah Donnelly, MA

Contributors:
Adrienne Tanner, CIP

**Acknowledgement: Much of the preceding text has been reproduced verbatim or with slight modifications from the OHRP Revised Common Rule Q&As page on HHS.gov.*