UCLA OHRPP
Office of the Human Research Protection Program

Human Research News

February 12, 2019

Subject: **UCLA – 2018 Revised Common Rule Implementation**

Dear UCLA Research Community,

On January 21, 2019 the Federal Government implemented revised regulations that oversee research involving human participants (aka – The Revised Common Rule).

This memo is intended to supplement the information provided in the December 19, 2018 Human Research News memo and to summarize key variations in requirements and procedures that the UCLA OHRPP and investigators must adhere to for research approved, or determined exempt on or after January 21, 2019.

UCLA OHRPP Guidance is being updated to reflect the details of new and revised processes and will be released to campus as it is finalized. Of note, the Federal Government has provided limited guidance into interpreting the Revised Common Rule. As additional guidance is provided, we will continually update OHRPP guidance and procedure documents, and communicate key information to the research community as needed.

When the research invokes multiple regulatory frameworks (e.g., Common Rule, FDA, HIPAA), all will be applied following the procedures detailed in UCLA OHRPP Guidance and this memo.

Please note that this document will use the terminology "Pre-2018 Rule" for the Common Rule prior to January 21, 2019. "2018 Rule" or "Revised Common Rule" or "RCR" refers to the set of Federal Regulations for research approved on or after January 21, 2019. This terminology is consistent with Federal Regulations and guidance.

Further, this memo provides a summary of UCLA's Implementation of the following:

- **Transitioning Projects to the 2018 Revised Common Rule**
- **Continuing Review**
- **NEW Annual Principal Investigator ("PI") Assurances for Eligible Studies**
- **Exempt Determinations and Limited IRB Review**

- **Broad Consent**
- **Grant Congruency Review**
- **Commensurate Protections for Research that is not Federally Supported**
- **NEW General Requirements for Informed Consent – Key Information Summary**
- **NEW Basic and Additional Informed Consent Requirements**
- **NEW Investigator Responsibility: Consent Form Posting**

Thank you,

UCLA Office of the Human Research Protection Program
Contact Information

This message was originally sent via the Human Research News mailing list. If you would like to subscribe to future announcements, please send an e-mail to: investigators-l+subscribe@lists.ucla.edu. The subject line and body of the e-mail can be blank.

Transitioning Projects to the 2018 Revised Common Rule

Federal Regulations allow any research approved prior to January 21, 2018 to continue to follow the pre-2018 rule for the life of the research project.

In order to minimize burden on the research community and additional work for IRB staff and reviewers, the UCLA OHRPP will transition projects approved under the pre-2018 Rule to the RCR on a case-by-case basis only, as studies that move will need to comply with all aspects of the RCR, and (in some cases) will require changes to the submission by the investigator.

Continuing Review

The RCR modifies when continuing review is required. Unless the UCLA IRB determines otherwise, continuing review of research is not required for research subject to the revised Common Rule in the following circumstances:

1. Research eligible for expedited review in accordance with 45 CFR 46.110;
2. Research reviewed by the IRB in accordance with limited IRB review as described in Section 3;
3. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
   a. Data analysis, including analysis of identifiable private information or identifiable biospecimens, **or**
   b. Accessing follow-up clinical data from procedures that participants would undergo as part of clinical care

Note: For FDA and DOJ regulated studies, annual continuing review continues to be required.

UCLA IRB may determine that continuing review is required for any research protocol that falls within the above criteria. *(The following is not required but provided as an example of factors an IRB may take into consideration.)* For example, the IRB may determine that continuing review is required when:

1. Required by other applicable regulations (e.g., FDA);
2. The research involves topics, procedures, or data that may be considered sensitive or controversial;
3. The research involves particularly vulnerable participants or circumstances that increase participants' vulnerability; or
4. An investigator has a history of noncompliance.

When the UCLA IRB determines that continuing review is required for such research, it will document the requirement to the investigator in the IRB determination letter.

NEW Annual Principal Investigator ("PI") Assurances for Eligible Studies

UCLA Principal Investigators of projects that are eligible for no annual continuing review **will** be required to complete Annual PI Assurances within the webIRB submission system.

The Annual PI Assurances process will enable the OHRPP to collect the information needed by the University to be able to identify active research projects. This process will be applicable to research approved on or after January 21, 2019 where the IRB determines that annual continuing review is not required. *UCLA OHRPP Guidance is being updated to outline additional details of the Annual PI Assurances process*.

Exempt Determinations and Limited IRB Review

All review level determinations, including determinations of Exemption, will continue to be made by UCLA OHRPP.

When the research requires limited IRB review or a HIPAA determination (i.e., waivers or alterations of the requirement for HIPAA authorization), the review will be conducted by the IRB Chair or a Chair-designated member of the IRB and may be conducted using expedited review procedures. As with all other research subject to IRB review requirements, when conducting limited IRB review the IRB has the authority to approve, require modifications in (to secure approval), or disapprove all research activities.

The Revised Common Rule includes eight categories, outlined at 45 CFR 46.104(d). Research activities in which the only involvement of human participants falls within one or more of the

categories outlined at 45 CFR 46.104(d) may qualify for exemption determination. Click here for **a complete list of the exempt categories outlined in the 2018 Rule.**

Note: At UCLA, exempt categories 7 and 8 will not be implemented.

Applications Certified Exempt prior to January 21, 2019 were certified under the six categories outlined in the pre-2018 Rule at 45 CFR 46.101(b).

Broad Consent

UCLA will not be implementing broad consent at this time.

The HHS Secretary's Advisory Committee on Human Research Protections (SACHRP) has been charged with developing a proposed guidance document to provide recommendations for the interpretation and implementation of the broad consent provisions of the Final Rule.
Please see SACHRP recommendations here.

Grant Congruency Review

The revised Common Rule removes the requirement that the IRB review the Federal grant application or proposal for consistency with the protocol submitted to the IRB. As this remains a University responsibility, the responsibility for grant congruency review will remain within OHRPP until further notice. This responsibility may be revised in the future upon receipt of written guidance from the federal Office for Human Research Protections (OHRP).

Commensurate Protections for Research that is not Federally Supported

The Revised Common Rule applies to research involving human participants that is supported by the US Department of Health and Human Services (HHS) and the fifteen other Federal agencies that have endorsed the Revised Common Rule. UCLA will continue to afford protections commensurate with those required by federal law to human research projects that are not federally supported.
UCLA OHRPP Guidance is being updated to outline additional details.

NEW General Requirements for Informed Consent – Key Information Summary

UCLA OHRPP Consent Templates are being updated to include 2018 Revised Common Rule requirements.

In addition to the requirements for obtaining informed consent and the consent process described in the UCLA OHRPP Guidance, the following specific requirements for consent, whether written or oral, apply to research subject to the 2018 Revised Common Rule:

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. Generally, the beginning of an informed consent should include a **concise** explanation of the following:

1. The fact that consent is being sought for research and that participation is voluntary
2. The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research;
3. The reasonably foreseeable risks or discomforts to the prospective subject;
4. The benefits to the prospective subject or to others that may reasonably be expected from the research; and
5. Appropriate alternative procedures or courses of treatment, if any that might be advantageous to the prospective subject.

NEW Basic and Additional Informed Consent Requirements

Note: UCLA OHRPP Consent Templates are being updated to include 2018 Revised Common Rule requirements.

In addition to the elements of informed consent described in UCLA OHRPP Guidance, the following additional elements are required for research subject to the 2018 Revised Common Rule. *UCLA OHRPP Guidance is being updated to outline additional details; OHRPP staff will communicate requirements to research staff during the IRB review process.*

Basic Elements [45 CFR 46.116(b)]

1. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

    a. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
    b. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional Elements (must be included when appropriate) [45 CFR 46.116(c)]

1. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
2. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;
3. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

NEW Investigator Responsibility: Consent Form Posting

The revised Common Rule includes a requirement for the posting of one IRB-approved consent form to a publicly available Federal website for each clinical trial conducted or supported by a Common Rule department or agency after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject.

The RCR defines a clinical trial as 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 the interventions on biomedical or behavioral health-related outcomes."*

This requirement may be satisfied by either the awardee or the Federal department or agency. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal website (e.g., confidential commercial information), the department or agency may permit or require redactions to the information posted.

The Office of Human Research Protections (OHRP) has announced that these consent forms must be posted either on clinicaltrials.gov or to a docket folder on regulations.gov.