

FALL 2015

**SPECIAL EDITION—Proposed Changes to Common Rule (NPRM)**

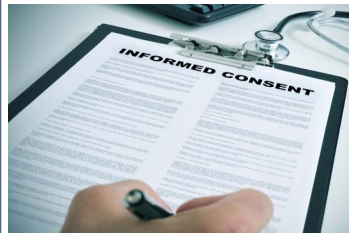
**Inside this issue:**

|   |                 |
|---|-----------------|
| <p><b>Informed Consent</b></p>  | <p><b>1</b></p> |
| <p><b>Biospecimen<br/>Single IRB<br/>Review<br/>Continuing<br/>Review</b></p>                                       | <p><b>2</b></p> |
| <p><b>Excluded and<br/>Exempt<br/>Research<br/>Waiver of<br/>Consent</b></p>  | <p><b>3</b></p> |
| <p><b>HRP Staff<br/>Contact<br/>Information<br/><br/>and<br/><br/>Reminder:<br/>NPRM<br/>Comment<br/>Period</b></p> | <p><b>4</b></p> |



On September 2, 2015, the U.S. Department of Health and Human Services (HHS) and 15 other Federal Departments and Agencies released a Notice of Proposed Rulemaking (NPRM) recommending significant changes to the Federal Policy for the Protection of Human Subjects, known as the Common Rule. The purpose for proposed revisions to the Common Rule is to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects. These are the first substantial proposed revisions to the Common Rule since its release in 1991. The proposed changes to the regulations have implications for researchers, research institutions, institutional review boards, and the sponsors of clinical research.

The most significant proposed changes are delineated in this Special Edition News Brief.



**INFORMED CONSENT:**

Due to the shifts in science, technology, and public health engagement with research participants, the Department of Health and Human Services (HHS) is undertaking a re-evaluation of the fundamental ethical principles that underlie the Common Rule. The goals of the Notice of Proposed Rule Making (NPRM) are to:

**increase human subjects' ability and opportunity to make informed consent decisions; better protect research subjects' trust relating to informed consent; increased transparency; impose strict new requirements on information that must be given to prospective subjects; and the manner in which information is given to participants to better assure an informed decision before enrollment.**

**The proposal calls for a requirement of the final version of the consent form to be posted on a public federal website. In addition, consent forms would no longer be unduly long documents and the important information will be easier to find; with more appropriate details provided about the research that is most relevant to a person's decision to participate. The presentation of the form should highlight key information. Further, informed consent would be required for secondary research with a biospecimen even if the investigator is not given information that would enable identification of whose biospecimen it is. Such consent would not need to be obtained for each research use of the biospecimen, but rather could be obtained using a "broad" consent form to future unspecified research uses.** The goal of new transparency aims to minimize the possibility of coercion and underlies a true compliance with the spirit of Informed Consent regulations.



### **USE OF BIOSPECIMENS:**

The proposed NPRM seeks to modify the definition of “human subject” to include all uses of biospecimens by an investigator conducting research. This approach would explicitly add the use of biological samples as an element of human subject research and thereby remove the controversial exercise of trying to determine whether a biospecimen may be identifiable now or in the future. The consequence of this modification is that most future uses of biospecimens require at least a broad informed consent for future use that is obtained either at the point of collection or prior to the subsequent use. The NPRM's motivation for this modification is to increase the public's trust and sense of partnership in this expanding area of research, which is expected to lead to improved treatment plans and breakthrough new therapies. The modified definition of human subject will be enforced three years after publication of the final rule and only to biospecimens that are collected prospectively from that enforcement date.

### **SINGLE IRB REVIEW:**

One of the boldest proposals of the NPRM is to mandate that only one IRB can act as the IRB of record for U.S. sites participating in a multi-site study. Policymakers have been encouraging this change for years, and the National Institutes of Health presaged this proposal late last year by publishing draft policy that promotes the use of a single IRB of record for multi-site NIH studies. The proposed regulation specifies that the funding department or agency would be responsible for choosing the IRB of record, and for studies with no funding agency the lead institution conducting the research would be responsible. Under the proposed rules, the requirement for a single IRB of record would not apply to: (1) cooperative research for which more than single IRB review is required by law (e.g., FDA-regulated devices); or (2) research for which the Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular study. The NPRM acknowledges that many institutions will have to implement policy and procedure changes in order to be able to outsource ethics review to a single IRB of record. For this reason, the NPRM proposes that the requirement for a single IRB of record should not take effect for three years from publication of the final rule.

### **CONTINUING REVIEW:**

The NPRM proposes eliminating continuing review in at least three situations:

- For minimal risk studies that qualify for expedited review, unless a reviewer documents why CR should take place.
- For studies that were reviewed by a convened IRB but have reached a stage of only (1) analyzing data (even if it is identifiable private information); (2) accessing follow-up clinical data from standard care procedures; or (3) doing both.
- For certain secondary research using information and biospecimens, under new limited IRB review provisions.

Administratively, an IRB still must receive annual confirmation that such research is ongoing and that no changes have been made that would require CR. Similarly, the NPRM does not change investigators' reporting obligations including changes to the protocol and unanticipated problems. The NPRM states that the administrative process could be as simple as an automated electronic communication in which the investigator types “Yes” to indicate that the study is ongoing without change.

**ACTIVITIES EXCLUDED FROM IRB REVIEW:**

The NPRM creates a new section of regulations that would exclude certain activities from the requirements of the Common Rule.

Institutional activities that do not clearly meet the definition of research:

- program improvement
- oral history, journalism, biography, and historical scholarship
- criminal justice

Activities that have non-research purposes:

- quality assurance and quality improvement
- public health surveillance
- intelligence surveillance

Activities that are low-risk and are already subject to independent controls

- educational test, survey procedures, interview procedures, or observation of public behaviors
- research involving collection or study of information that has or will be collected
- research conducted by a government agency using government-generated or government-collected data
- activities regulated by HIPAA

**EXEMPT RESEARCH:**

A new process would allow studies to be determined to be exempt without requiring any administrative or IRB review. [Certain exempt and all non-exempt research would be required to provide privacy safeguards for biospecimens and identifiable private information.]

New categories include:

- certain research involving benign interventions with adult subjects
- research involving educational tests, surveys, interviews or observations of public behavior when sensitive information may be collected, provided that data security and information privacy protections policies are followed
- secondary research use of identifiable private information originally collected as part of a non-research activity, where notice of such possible use was given
- storing or maintaining biospecimens and identifiable private information for future, unspecified secondary research studies, or conducting such studies, when a broad consent template to be promulgated by the Secretary of HHS is used, information and biospecimen privacy safeguards are followed, and limited IRB approval of the consent process used is obtained

**WAIVER OF CONSENT:**

The NPRM seeks to place new limits on an IRB's ability to waive or alter the consent procedure for research involving biospecimens. First, the NPRM proposes two new stringent waiver criteria for biospecimen research; the research must have a compelling scientific purpose and the research could not be conducted with other biospecimens for which informed consent was or could be obtained. Under this new, more stringent waiver standard, the circumstances in which a waiver could be granted by an IRB should be extremely rare.

These limits aim to reinforce the ethical principle of respect for persons. They also will necessitate the obtaining of informed consent for the vast majority of biospecimen research. Importantly, the NPRM has considered the severity of such a requirement and endorses a new type of consent labeled as a "broad consent," which will have its own required elements and for which the Secretary of HHS will provide a template.



## NPRM COMMENT PERIOD

To be assured consideration, comments must be received by OHRP by 5 pm, December 7, 2015.

For additional information on the NPRM and to view OHRP videos addressing the primary changes noted in the NPRM, open the following URL badge (ctrl + click). Instructions to provide comments directly to OHRP are also available on this webpage:



You may also submit your comments to the UCI Office of Research , HRP, at: [UCI-NPRM@uci.edu](mailto:UCI-NPRM@uci.edu).

Comments will be compiled and sent to OHRP by December 7th.



### HUMAN RESEARCH PROTECTIONS

**U.S. Mail:**

Office of Research  
University of California, Irvine  
5171 California Ave., Suite 150  
Irvine, CA 92697-7600

**The Office is Open:**

Monday—Friday  
8am—5pm

**General Email:**

[IRB@research.uci.edu](mailto:IRB@research.uci.edu)

[Human Research Protections Webpage](#)

[IRB Fast Facts](#)

#### Institutional Review Board 'A' Biomedical

IRB Chair: Tahseen Mozaffar, MD

Mihaela Nistor, CIP  
Administrator  
949-824-3711  
[mnistor@uci.edu](mailto:mnistor@uci.edu)

Joy Chu  
Senior Analyst  
949-824-3367  
[joy.chu@uci.edu](mailto:joy.chu@uci.edu)

Kirsten McDaniel  
Analyst  
949-824-6068  
[k.mcdaniel@uci.edu](mailto:k.mcdaniel@uci.edu)

---

#### Institutional Review Board 'B' Biomedical

IRB Chair: Kenneth Linden, MD, PhD

Rachna Singh, MS, CCRP  
Administrator  
949-824-2576  
[rachnas@uci.edu](mailto:rachnas@uci.edu)

Melissa Eng, CIP  
Senior Analyst  
949-824-5622  
[melisse@uci.edu](mailto:melisse@uci.edu)

Theresa Sanchez  
Analyst  
949-824-2125  
[tmsanche@uci.edu](mailto:tmsanche@uci.edu)

---

#### Institutional Review Board 'C' Social - Behavioral

IRB Chair: Elizabeth Cauffman, PhD

Valerie Sanchez, MA, CCRP  
Administrator  
949-824-4779  
[valerie.ms@uci.edu](mailto:valerie.ms@uci.edu)

Melissa Camarena  
Senior Analyst  
949-824-7114  
[mccamare@uci.edu](mailto:mccamare@uci.edu)

Roy Taggug  
Analyst  
949-824-6662  
[rtaggug@uci.edu](mailto:rtaggug@uci.edu)

#### IRB Team 'D' Biomedical Expedited and Exempt

Matt Kinder, CIP  
Administrator  
949-824-9819  
[mkinder@uci.edu](mailto:mkinder@uci.edu)

Le'Quan Jackson  
Senior Analyst  
949-824-5047  
[ldjackso@uci.edu](mailto:ldjackso@uci.edu)

OPEN  
Analyst  
949-824-0665

---

Karen Allen, MA, CIP  
Director  
Research Protections  
949-824-1558  
[karen.allen@uci.edu](mailto:karen.allen@uci.edu)

Beverley Alberola, CIP  
Associate Director  
Research Protections  
949-824-5746  
[beverley.alberola@uci.edu](mailto:beverley.alberola@uci.edu)

Laverne Estañol, MS, CHRC, CIP, CCRP  
Assistant Director  
Human Research Protections  
949-824-4704  
[lestanol@uci.edu](mailto:lestanol@uci.edu)

Jessica Sheldon, CIP  
EQUIP Administrator  
Human Research Protections  
949-824-3831  
[jessica.sheldon@uci.edu](mailto:jessica.sheldon@uci.edu)

Debbie Melamud, MPH  
Administrator  
Human Research Protections  
[debbie.melamud@uci.edu](mailto:debbie.melamud@uci.edu)

Cathryn Lucas, CIP  
Administrator  
Human Research Protections  
949-824-7735  
[cathryn.lucas@uci.edu](mailto:cathryn.lucas@uci.edu)