THE UNIVERSITY OF IOWA

OFFICE OF THE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT

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To: University of Iowa Research Community
From: Heather Gipson
Assistant Vice President for Research Compliance

RE: U.S. Department of Health & Human Services (HHS) Notice of Proposed Rulemaking (NPRM)

On Tuesday, September 8, 2015 the U.S. Department of Health & Human Services (HHS) released a Notice of Proposed Rulemaking (NPRM) aimed at updating 45 CFR 46 (the Common Rule for human subject protections in research). To link directly to the NPRM please go to: http://www.hhs.gov/ohrp/humansubjects/regulations/nprmhome.html

Significant changes have been proposed and HHS is seeking public comment regarding these changes. We would like to encourage faculty and staff to provide feedback. All comments must be received by HHS no later than 5:00 p.m. on December 7, 2015. You may provide feedback either directly to HHS as individuals or groups or you may provide feedback to the Office for the Vice President of Research & Economic Development for inclusion in our institutional response.

The following list encompasses the most significant changes to the Common Rule proposed in the NPRM as described by HHS:

1. Improve informed consent by increasing transparency and by imposing stricter new requirements regarding the information that must be given to prospective subjects, and the manner in which it is given to them, to better assure that subjects are appropriately informed before they decide to enroll in a research study.

2. Generally require informed consent for the use of stored biospecimens in secondary research (for example, part of a blood sample that is left over after being drawn for clinical purposes), even if the investigator is not being given information that would enable him or her to identify whose biospecimen it is. That consent would generally be obtained by means of broad consent (i.e., consent for future, unspecified research studies) to the storage and eventual research use of biospecimens.

3. Exclude from coverage under the Common Rule certain categories of activities that should be deemed not to be research, are inherently low risk, or where protections similar to those usually provided by IRB review are separately mandated.

4. Add additional categories of exempt research to accommodate changes in the scientific landscape and to better calibrate the level of review to the level of risk involved in the 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:

a. certain research involving benign interventions with adult subjects;

b. 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;

c. secondary research use of identifiable private information originally collected as part of a non-research activity, where notice of such possible use was given;

d. 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.

5. Change the conditions and requirements for waiver or alteration of consent such that waiver of consent for research involving biospecimens (regardless of identifiability) will occur only in very rare circumstances.

6. Mandate that U.S. institutions engaged in cooperative research rely on a single IRB for that portion of the research that takes place within the United States, with certain exceptions. To encourage the use of IRBs that are otherwise not affiliated with or operated by an assurance-holding institution ("unaffiliated IRBs"), this NPRM also includes a proposal that would hold such IRBs directly responsible for compliance with the Common Rule.

7. Eliminate the continuing review requirement for studies that undergo expedited review and for studies that have completed study interventions and are merely analyzing data or involve only observational follow-up in conjunction with standard clinical care.

8. Extend the scope of the policy to cover all clinical trials, regardless of funding source, conducted at a U.S. institution that receives federal funding for non-exempt human subjects research.

How to submit a comment regarding the NPRM directly to HHS:

- You may submit comments in one of three ways (no duplicates, please):

    1. *Electronically*. You may submit electronic comments on specific issues in this regulation. (You can type comments directly in a box and/or include attachments. Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

        - In another tab or window, access www.regulations.gov:

- Copy and paste, or just retype, the docket number HHS–OPHS–2015–0008 into the regulations.gov box that is labeled “Search”.
- The first answer should say “Featured Result.”
- Click on “Comment Now” button to the right of the notice title.

2. *By mail*. You may mail written comments (one original and two copies) to the following address ONLY: Office for Human Research Protections (OHRP), 1101 Wootton Parkway, Suite 200,Rockville, MD 20852. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier*. If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to the Office for Human Research Protections (OHRP), 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

How to submit comments to OVPR&ED:

- Please submit written comments via email to Heather Gipson at heather-gipson@uiowa.edu no later than Friday, November 20, 2015.

How to browse comments that have been submitted regarding the NPRM:

- In another tab or window, access www.regulations.gov:
- Copy and paste, or just retype, the docket number HHS–OPHS–2015–0008, into the regulations.gov box that is labeled “Search”.
- The first answer should say “Featured Result.”
- Click on “Open Docket Folder” at the upper right corner of that result.
- There should be a heading labeled “Comments” in the middle of the page.
- Click on “View All” next to Comments.
- Now you should have access to all of the comments, and can use the search box at the top to search among them.
- Also, a list of comments received and posted should display, and can be opened one at a time.

For many comments, the substance of the comment is in an attachment, which can be opened by clicking on the "View Attachment" PDF icon on the right side of the screen.

For additional questions please contact Heather Gipson, Assistant Vice President for Research Compliance at 319.335.9546 or heather-gipson@uiowa.edu