

October 26, 2011

Jerry Menikoff, M.D., J.D.  
Office for Human Research Protections  
Department of Health & Human Services  
1101 Wooton Parkway, Suite 200  
Rockville, MD 20852

Re: Advanced Notice of Proposed Rulemaking for Human Subjects Protection

Dear Dr. Menikoff:

The University is pleased to comment on the July 2011 Advanced Notice of Proposed Rulemaking for Human Subject Protection (HHS-OPHS-2011-0005). While we agree that the Common Rule, essentially unchanged since it was adopted in 1991, does not completely address contemporary practice, along with the guiding principles articulated in the Belmont Report, it does largely serve to protect human subjects. Investigators, institutions, and Institutional Review Boards (IRBs) work hard to ensure that subjects who participate in research are protected and valued. We appreciate the Department's effort to modernize and streamline the current regulations. The background material in the ANPRM and the complexity of the questions raise multiple issues that we have tried to address in our comments. I have consulted with our faculty, administrators, and investigators involved in research, human subject protection, compliance, and privacy here at the University. Our comments represent the synthesis of opinions that were shared with me.

Attached to this letter is an appendix that provides responses to each of the questions posed in the ANPRM. Additionally, the University of Rochester would like to emphasize what we consider the four overriding issues:

1. The first goal of the ANPRM is investigator "relief." We wonder if changing the basic regulations that were designed to give protection to research subjects is the appropriate route for this goal.
2. We absolutely agree that the burdens on IRBs, researchers, organizations, sponsors, and others throughout the research enterprise need to be reduced; however, we caution that when proposing federal regulations, the least complex rules are preferred, as long as those measures achieve the important societal goals (e.g., the protection of human research subjects) that have been identified as requiring regulation.
3. Oversight (federal and institutional) should be appropriate to the potential risk of the research. We believe that one reason the current system is overly burdensome is that, by regulation, guidance, or interpretation, studies often receive the same level of review regardless of the potential risk to participants.
4. Conflicting regulations have long been a source of confusion, and these conflicts and differences have thwarted some research activities and have added burden without improving human subject protection.

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October 26, 2011

Page 2

An ANPRM issue that the University of Rochester wishes to highlight is our belief that the federal regulations should not require biospecimens to be considered as always identifiable. The impact on basic and clinical science would be staggering. Biospecimens that include DNA do not identify individuals without other linked information or a large database that contains the individual's specific DNA sequences. We also strongly believe that including biospecimens without identifiers within the human subject research regulations related to information risk would inappropriately expand the meaning of "human subject" and add unintended and unnecessary burden to the system of human subject research oversight. Neither de-identified data nor biospecimens without identifiers should be considered research involving "human subjects."

The University of Rochester supports the effort to update and improve the regulations and is committed to conducting science of the highest quality, with an expectation that all individuals involved with the Human Research Protection Program understand and apply their obligation to protect the rights and welfare of research subjects. Although the current regulations are deficient in some areas, they generally provide appropriate protections for research subjects. We believe that keeping most of the current regulatory framework with refinements and additions is the most reasonable approach. Harmonized guidance on implementation of the regulations would also help in reducing unnecessary burden on IRBs, researchers, and institutions. The University looks forward to continuing the multifaceted and vigorous national dialog on decreasing regulatory burden while improving human subject protection.

Thank you for considering our comments, and feel free to contact me if you have any questions.

Sincerely,

A handwritten signature in blue ink that reads "Ralph W. Kuncl". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Ralph W. Kuncl, Ph.D. M.D.  
Provost and Executive Vice President

Enclosure: University of Rochester Response to ANPRM (HHS-OPHS-2011-0005)

cc: Gary Chadwick, Director, UR Office for Human Subjects Protection  
Sue Stewart, Senior Vice President and General Counsel  
Gunta Lidars, Associate Vice President for Research Administration  
Thomas A. Pearson, Senior Associate Dean for Clinical Research, SMD