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Elisa A. Hurley, PhD
Executive Director

September 17, 2015

Submitted electronically at www.regulations.gov

Jerry Menikoff, MD, JD
Director, Office for Human Research Protections
US Department of Health and Human Services
1101 Wooton Parkway, Suite 200
Rockville, MD 20852

RE: Document 2015-21756, *Federal Policy for the Protection of Human Subjects* (80 *Federal Register* 53931)

Dear Dr. Menikoff:

Public Responsibility in Medicine and Research (PRIM&R), a nonprofit educational and professional development organization dedicated to advancing the highest ethical standards in the conduct of research, appreciates the United States Department of Health and Human Services' Office for Human Research Protections (OHRP) efforts to move forward the much-anticipated revisions to the Federal Policy for the Protection of Human Subjects.

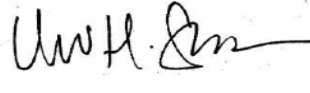
PRIM&R looks forward to sharing with OHRP its comments on the proposed changes. However, given the breadth and anticipated impact of the proposed changes, we do not think that the 90-day comment period will allow for the careful analysis and measured response from all corners of the research ethics community that these revisions warrant. Furthermore, the unusually large number of questions posed by the Notice of Proposed Rulemaking and the complexity and novelty of some of the solutions proposed, especially those related to biospecimens, merit public discussion and deliberation beyond what can be accomplished within the proposed comment period. Therefore, PRIM&R requests that the comment period be extended to 120 days (ending on January 6, 2016) to allow all interested parties sufficient opportunity to discuss and craft thoughtful comments that will assist the Federal government in this critical rulemaking process.

We thank you for your consideration of this request, on which we hope you will make a decision as soon as possible. If you have any questions or require any further information, please feel free to contact PRIM&R's executive director, Elisa A. Hurley, PhD, at (617) 423-4112 or ehurley@primr.org.

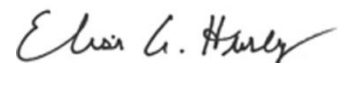
Respectfully Submitted,



Alexander M. Capron
Chair, Board of Directors



David H. Strauss, MD
Chair, Public Policy Committee



Elisa A. Hurley, PhD
Executive Director

cc: Public Policy Committee
Board of Directors