



August 4, 2011

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

Re: Request for extension to comment period on advance notice of proposed rulemaking on human subjects research protections

Dear Dr. Menikoff:

Public Responsibility in Medicine and Research (PRIM&R), a non-profit organization dedicated to advancing the highest ethical standards in the conduct of research, appreciates the efforts of the United States Department of Health and Human Services' Office for Human Research Protections (OHRP) to undertake the substantial and much-anticipated task of revising federal regulations for human subjects research. PRIM&R looks forward to sharing its comments on the advance notice of proposed rulemaking (ANPRM) that was published on July 26, 2011. However, we are concerned that the 60-day comment period may prove insufficient to allow for an appropriately careful analysis and full response from all corners of the research ethics community.

The recently released ANPRM is ambitious in its scope, addressing a broad range of issues with a number of proposals that vary in their specificity. PRIM&R applauds OHRP's efforts at comprehensive reform of the Common Rule. But we believe the breadth of the ANPRM's content warrants a particularly deliberate and in-depth review before any attempt is made to submit comments. Given the number of questions posed in the ANPRM, as well as the breadth of many those questions, PRIM&R is concerned that the 60-day timeframe will prove inadequate to allow members of the research ethics community, including our committee that was composed to respond to the ANPRM, to develop and articulate the thorough and measured response that the ANPRM warrants.

This is exacerbated by the fact that many of the individuals who have expertise and interest in commenting come from academic institutions. The typical academic schedule takes many scholars and researchers away from their core professional activities during August, with the result that the 60-day comment period is effectively substantially shortened. The absence of this professional group may skew responses toward the opinions of professional lobbyists who work through the summer. While such opinions are no less valid than those of academics, it is important that the full range of interested parties be given equal voice in the rulemaking process. Dissatisfaction with the Common Rule has many causes, many of them based on individual's experiences with the application of particular provision; some of these will point in one direction, some in another, but it is important that they all be heard, and they may not be adequately

conveyed by those who speak for associations and organizations, even ones as broadly based in the IRB community as PRIM&R.

The responses to the ANPRM will set the agenda for the fuller proposed revisions of the regulations, and we respectfully suggest that the 60-day comment period is simply not a realistic deadline for deliberate and thoughtful input from a wide array of constituencies at this critical point in the process. Therefore, PRIM&R joins others in the professional community in requesting that the comment period be extended to 120 days (ending on November 24, 2011) so that all interested parties may be given sufficient opportunity to craft detailed and thoughtful comments, and thus to lend their assistance to the Federal government in this critical rulemaking process.

In closing, PRIM&R hopes OHRP will accept this request for an extension of the comment period. Thank you for your consideration, and if you have any questions or desire clarification, please feel free to contact us at 617.423.4112, extension 0.

Respectfully submitted,

A handwritten signature in cursive script that reads "Joan Rachlin".

Joan Rachlin, JD, MPH  
Executive Director  
Public Responsibility in Medicine and Research (PRIM&R)

cc: PRIM&R Board of Directors, PRIM&R Public Policy Committee