



**Rush D. Holt**

Chief Executive Officer and  
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January 4, 2016

Jerry Menikoff, M.D., J.D.  
Office for Human Research Protections  
Department of Health and Human Services

Re: Federal Policy for the Protection of Human Subjects  
HHS– OPHS–2015–0008  
Submitted via [www.regulations.gov](http://www.regulations.gov)

Dear Dr. Menikoff:

On behalf of the American Association for the Advancement of Science (AAAS), the world's largest multidisciplinary science society, we welcome the opportunity to comment on the Notice of Proposed Rulemaking (NPRM) on the protection of human research subjects. AAAS has a longstanding interest and expertise in research ethics. We support the thrust of the NPRM, which recognizes the need for balancing the goals of protecting human subjects and allowing research to proceed without burdensome restrictions that provide little value. We offer the following comments on a few issues that have broad implications, and recommend that you review the comments submitted by a number of our affiliates, which feature more specific details and feedback pertaining to their respective scientific disciplines.

### **Improving the Informed Consent Process**

It is paramount that research subjects understand the research to which they are giving consent; thus, we strongly support the effort to encourage clearer consent forms and the streamlining of the informed consent process to its most important elements. Informed consent goes beyond just the form. Researchers should be able to pursue creative ways to convey the necessary information to subjects and to evaluate their understanding.

### **Biospecimens**

In the 2011 Advance Notice of Proposed Rulemaking (ANPRM), we supported the reasoning behind obtaining general consent for further research use of biospecimens based on the awareness that it is possible, though unlikely, to re-identify data and biospecimens that have been de-identified. However, we noted the potentially heavy administrative burden when biospecimens are collected, particularly in a clinical or other non-research setting. To avoid an excessive burden, we suggested that the new consent rules be applied prospectively only, grandfathering in biospecimens already collected. Thus we are pleased that the NPRM applies only to research involving biospecimens collected in the future.

Our interest lies in supporting science to advance society; that means conducting research that is ethical and also efficient. We are receptive to the idea that in this era of precision medicine, research participants increasingly want to be considered research partners rather than research subjects. However, given the complexities of the biospecimens issue, it is worth considering addressing it through timely guidance rather than through changes to the Common Rule, particularly to enable more rapid and flexible response in an ever-changing technological climate.

### **Single IRBs for Multi-Site Research**

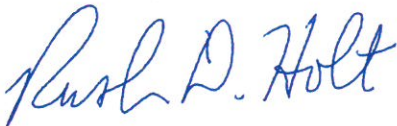
In general, there is clear value in moving toward single institutional review boards (IRBs) for multi-site research to reduce administrative burden. But costs should be considered when crafting and implementing this policy. For further detail on the issue of administrative burden (in this and all areas of the NPRM), we recommend that you review the comments of the research institutions and the umbrella groups that represent them, such as the Association of American Universities, Association of Public and Land-grant Universities, and Council On Governmental Relations.

### **Additional Considerations**

Much remains in the NPRM to be more defined, including certain terms (e.g., biospecimens) and to-be-developed templates and tools. We encourage OHRP to continue to engage stakeholders and consider partnering with other leaders in the field as it develops these.

We commend OHRP for moving forward in the complex process of updating the Common Rule. AAAS stands ready to assist you as you consider the vitally important questions and challenges pertaining to the protection of human research subjects.

Sincerely,



Rush Holt