EO 12866 Regulatory Review of RIN 0937-AA02

Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators

About Public Responsibility in Medicine and Research (PRIM&R)

- 41-year-old nonprofit educational and professional development organization dedicated to advancing the highest ethical standards in the conduct of research through education, membership services, professional certification, public policy initiatives, and community building.
- Source of balanced, thorough, and accurate information on the range of ethical and regulatory issues affecting research, serving individuals and organizations involved in biomedical, behavioral, and social science research, particularly the members and staff of human research protections programs and institutional review boards (IRBs).

Key Considerations for Revisions to the Federal Policy for the Protection of Human Research Subjects (hereafter Federal Policy)

I. Harmonization of Regulatory Requirements

A stated goal of the Department of Health and Human Services’ 2011 Advance Notice of Proposed Rulemaking was to improve harmonization amongst regulatory requirements of different funding agencies. PRIM&R applauds this goal, and believes it is essential that any revisions to the Federal Policy be endorsed by all Common Rule agencies; the adoption of any new regulatory framework by a single agency will undermine efforts toward harmonization, increase confusion and burden, and, ultimately, weaken subject protections.

II. Registration of Additional Protections

Institutions should always be permitted to add additional protections to the minimal regulatory requirements as they see fit. The current Federal Policy is written broadly in part to allow institutions flexibility in how they interpret and apply the regulations. Requiring institutions to register additional protections would not only dramatically increase regulatory burden, but also constitutes a fundamental misunderstanding of the relationship between the baseline research requirements set by the federal government and what an institution determines it will do to protect the subjects of its research.

III. Centralized Review for Multi-Site Studies

In principle, we favor a system of centralized review for multi-site studies as a means of reducing inefficiencies in the current research review system that do not enhance the protection of human subjects. However, we do not support mandating a single IRB of record for all multi-site studies, given the many unanswered procedural questions and logistical challenges (e.g., about time, resources, and costs involved) associated with
developing a central review process. The field requires more time to conduct research on the use of single IRBs, to develop guidance, and to disseminate best practices before the use of a single IRB for multi-center studies is mandated.

IV. **Defining the Boundaries of Research**

There is a sense in the research community that IRBs have expanded their scope to encompass activities that were not intended to, or may not need to, fall under their purview, including quality improvement activities, pragmatic clinical trials, and clinical innovation. As a result of this lack of clarity about the types of activities that require IRB oversight, there are considerable inefficiencies in the current research oversight system. To address this, PRIM&R strongly believes that any revisions to the Federal Policy at this time must include a clear framework for delineating the types of activities that are subject to IRB review.

**Additional Readings**

Copies of the following documents have been provided for your review:


- PRIM&R’s Response to the Office for Human Research Protections’ 2014 *Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care*

- PRIM&R’s Response to the National Institutes of Health’s 2014 *Draft Policy on the Use of a Single Institutional Review Board for Multi-Site Research*

We also invite you to learn about PRIM&R’s Project on the Boundary Between Research and Practice, which provides guidance on making decisions regarding the need for ethical review or oversight of health-related activities conducted along the boundary between research and practice. Information about this initiative, as well as the resulting white paper and appendices, can be found at: [http://www.primr.org/publicpolicy/boundaries/](http://www.primr.org/publicpolicy/boundaries/).