January 29, 2015 Submitted by email to singleIRBpolicy@mail.nih.gov

Francis S. Collins, MD, PhD
Director
National Institutes of Health
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Dear Dr. Collins:


For 40 years, PRIM&R has been dedicated to advancing the highest ethical standards in the conduct of research. We accomplish this goal by serving the full array of individuals and organizations involved in biomedical, behavioral, and social science research, particularly the members and staff of human research protection programs (HRPPs) and institutional review boards (IRBs). Through conferences and other educational activities, PRIM&R provides balanced, thorough, and accurate information on a range of ethical and regulatory issues affecting research.

The biomedical research landscape has evolved dramatically since the publication of the federal regulations for the protection of human subjects in 1974. In particular, research with human subjects has become an increasingly complex endeavor in which multi-center rather than institution-based research is increasingly the norm. In light of this shift, it is sensible to consider whether an alternative structure for research review better safeguards the rights and welfare of research participants and lessens unnecessary administrative burden. To that end, we understand the NIH’s interest in reducing inefficiencies associated with multiple IRB review by mandating that studies involving multiple institutions rely on a single IRB for review.

However, while the use of a single IRB can be a beneficial approach for some multi-site studies, PRIM&R believes that it is premature and perhaps inappropriate to mandate single IRB review for all NIH-funded and conducted studies. Many factors influence whether the use of a single IRB serves the interests of greater efficiency, reduced costs, and stronger
protections for subjects. Such factors include the number and types of institutions involved, the study design, the degree of risk created for subjects (e.g., minimal risk or greater than minimal risk), the nature of the study team, and the resources available for investigators and local sites.

Further, reliable empirical data on the various ways in which a single IRB can be used to provide ethical review of multi-site research, and on whether such review is better, from the perspective of subject protections, administrative costs, efficiency, and quality of review, than relying on local IRBs, are sparse to nonexistent. In the absence of sufficient evidence, we believe that a policy requiring the use of single IRBs for all domestic sites of multi-site NIH-funded studies is premature and ill advised. As in medicine, innovations in policies should be preceded by research and supported by adequate data. We understand that the NIH is currently investing in research directed at answering some of the relevant empirical questions related to the use of a single IRB, as well as alternative models for improving IRB efficiency. Accordingly, it would seem prudent to await the results of these studies prior to promulgating such a policy.

The mandated use of a single IRB is associated with many as yet unanswered procedural questions and logistical challenges. For instance, institutions tasked with serving as the single IRB of record will need to have sufficient infrastructure to manage the network of participating institutions. The development of such an infrastructure is likely to involve considerable time, resources, and costs. It is unclear from the draft policy who would bear those costs. Similarly, while the use of a single IRB may be familiar to some institutions, it is likely to be unfamiliar to most. The field requires more time to conduct research on the use of a single IRB, to develop guidance, and to disseminate best practices before the use of a single IRB for multi-center studies is mandated.

As stated at the outset, we recognize the value of streamlined and efficient IRB review and the use of a single IRB for some multi-site research. However, instead of mandating single IRB review for all studies at this time, we urge the NIH to consider incentives to encourage voluntary adoption. The NIH and others should also promote the development of tools and resources to guide institutions through the process of both building the required infrastructure and crafting policies and procedures for managing or working through a single IRB. Finally, the NIH ought to support the conduct of empirical research on the costs and benefits associated with the use of the single IRB mechanism. PRIM&R believes that taken together, these are the most appropriate means for the NIH to foster the stated purposes of the draft policy, namely, “to increase the use of single IRBs for multi-site studies funded by the NIH.”

Below, then, are several examples of activities we encourage the NIH to consider in its effort to support the wider use of the single IRB mechanism for multi-site studies:

1. Convene an expert panel to host open meetings to develop criteria regarding the types of research that lend themselves to the single IRB model and those that do not;
2. Sponsor research on existing models of review by a single IRB for multi-site research to gather more evidence about both the quality and cost of review;
3. Create incentives (e.g., preferential treatment in the award process) that encourage and reward the use of, and require the collection of data on the use of, single IRB review and/or elements of single IRB review processes; and

4. Develop tools, guidance, and best practices to help facilitate the use of single IRB review mechanisms (e.g., model reliance agreements, standard operating procedures, etc.)

Finally, we wish to raise concerns about how the adoption of this policy may impact harmonization efforts. The provisions put forward in the NIH’s draft policy are in line with changes first proposed in the Department of Health and Human Services’ 2011 Advance Notice of Proposed Rulemaking (ANPRM), entitled *Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators*. That ANPRM sought to update the federal regulations for the protection of human subjects and strengthen harmonization amongst the regulatory agencies involved. However, with the status of DHHS’ proposed rule unclear, we are concerned that the NIH’s adoption of policies originally proposed under the framework of the ANPRM may worsen a piecemeal approach to regulatory change and undermine harmonization amongst regulatory requirements from different funding agencies, which may, in turn, cause confusion and, ultimately, weaken subjects protections.

PRIM&R is grateful to the NIH for the opportunity to comment, and we hope that you and your colleagues will find our input on this matter useful as you finalize this policy. If you have any questions or require any further information, please feel free to contact me at (213) 740-2557 or PRIM&R’s executive director, Elisa A. Hurley, PhD, at (617) 423-4112 or ehurley@primr.org.

Respectfully Submitted,

[Signature]

Alexander M. Capron
Board Chair

c: Board of Directors
Executive Director