

January 29, 2015

Sarah Carr
Acting Director of the Office of Clinical Research and Bioethics Policy
Office of Science Policy
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Dear Director Carr,

The Association of American Universities (AAU) and the Association of Public and Land-grant Universities (APLU) welcome the opportunity to provide feedback to the National Institutes of Health (NIH) on the “Draft NIH Policy on the Use of a Single Institutional Review Board (IRB) for Multi-Site Research” (NOT-OD-15-026). AAU and APLU together represent most of the major public and private research universities in the United States, all of which are engaged in research involving human subjects affected by the proposed policy.

First and foremost, AAU and APLU applaud NIH’s effort to streamline regulations in order to improve efficiency without compromising the protection of human subjects. The administrative burden across the research enterprise has grown appreciably due to a significant increase in regulations and reporting obligations promulgated by Federal agencies and a lack of harmonization among those regulations. Policies and regulations related to human subjects protection are among the most frequently cited causes of the increased burden and cost associated with research, and certainly the inefficiencies caused by duplication of IRB review in multi-site trials is a substantial part of that.

In the absence of revision of the Common Rule, AAU and APLU appreciate NIH’s leadership in beginning to address these issues. We also welcome the opportunities created by NIH to receive substantive input on this policy, and we encourage the agency to consider additional fora – such as a workshop or symposium during which success stories and lessons learned from current models of central IRBs could be discussed – before enactment of a final policy. AAU and APLU note that the administration of human subjects protections involves multiple entities on a university campus, ranging from senior research officers to compliance officers to general counsels, who may have different perspectives on the impact of this policy, depending on their responsibilities related to human subjects research.

AAU and APLU, in principle, support the movement towards the use of a single IRB for multi-site research studies. Many of our research institutions have embraced this model or participated in central IRB initiatives. That being said, we think NIH needs to move in a cautious, deliberative fashion in mandating the use of single IRBs, and we offer some principles below to consider. For the adoption of a single IRB model for multi-site studies to be successful, implementation of the policy must carefully take into account potential unintended, negative consequences. Because our member institutions have extensive experience with setting up and participating in central IRBs, and many are submitting detailed comments based on their own experiences, we encourage NIH to strongly consider the lessons that may be gleaned from those comments.

Principles to consider:

1. Creating a glide-path towards a mandate: As a practical matter, sometimes mandating change is the best way to make progress with systems that have been in place for a long period of time. As such, AAU and APLU hesitate to suggest that the use of single IRBs not be mandated, but rather be optional and incentivized. We agree with NIH's finding that the use of single IRBs for multi-site studies is currently under-utilized. However, we are concerned that the proposed policy would be too disruptive and costly if implemented at a rapid rate without giving institutions time to transition. As noted below, the movement towards a single IRB can take a substantial amount of time and resources. As such, NIH should consider some sort of phased-in approach to an ultimate mandatory policy, perhaps by starting with lower-risk studies or offering incentives for earlier, voluntary adoption. Another possibility would be by expanding the use of the NCI CIRB as a pilot before implementing the policy on a larger scale.
2. Formation of a central IRB is not an overnight event: It takes time to set up and smoothly administer a central IRB. The most successful models of a single IRB for multi-site trials, such as those developed by the University of California system or the NCI CIRB, took time to establish. It requires a tremendous amount of trust for institutions to rely on another IRB's review and that trusting relationship takes time to develop. The authorization agreements described by the draft policy will take a substantial amount of time to negotiate and are likely to evolve over time, as institutions become accustomed to new relationships and joint processes or procedures. We are concerned that the policy does not recognize the time and effort this endeavor will entail, and presents an overly simplified view of establishing a single IRB of record.
3. Infrastructure to support this effort must not be an unfunded mandate: In discussing the NIH policy with our institutions, AAU and APLU have found that while the use of a single IRB for multi-site studies has the potential for cost savings and reduction of burden when implemented well, reaching that point requires a substantial investment in supporting infrastructure. Establishing and maintaining a central IRB requires costly investment, including but not limited to the creation of electronic management systems that are interoperable between institutions, the adaptation of automated processes to multiple institutions, the communications tools necessary to link investigators and IRBs, the staff time necessary to develop agreements, consensus documents or standard operating procedures, and the interaction necessary to build and maintain trusting relationships between institutional officials. Even if an institution is not serving as the IRB of record, the infrastructure necessary to adapt existing human research protection programs software systems and protocols to participate in the centralized process has real financial implications. While the draft policy allows for IRB fees to be charged as part of the direct cost of the grant, institutions will have no way to recoup the costs of setting up the infrastructure necessary to administer participating in a central IRB. AAU and APLU urge NIH to avoid shifting this cost onto institutions that are already struggling with the considerable costs of research compliance. For example, could the agency create electronic tools or template documents that could ease the cost burden of participating institutions?
4. Reconsidering flexibility for local review: AAU and APLU acknowledge that there are a variety of reasons for why an institution might strongly support the need for local review. We agree that

some of these issues could probably be addressed, as described by the draft policy, through the use of ad hoc consultants or submission of additional information, and that others, such as how to deal with liability concerns related to subject injury, could be clarified in the details on the policy. However, there may be situations where a local IRB review is relevant and should allow for an exemption from the policy beyond the current exemption scope described. Examples could include well-documented local sensitivities to specific research or differing interpretations on ethical issues between partnering institutions. We do not expect that these would be frequent occurrences, but we do believe it is important that the policy leaves flexibility for exemption in the unique circumstances that will inevitably arise in a research enterprise as large and diverse as that supported by NIH.

5. The policy should not result in a multitude of central IRBs: The policy should explicitly state that its purpose is not to create a more complex system by promulgating a unique single IRB for every multi-site study. Managing multiple IRBs – as many as a different one for every multi-site study – would present a far greater cost and administrative burden for institutions and would seem to run counter to the intent of the policy.
6. Timing is everything: The policy needs to provide clarity in regards to the timing of IRB selection and approval relative to grant application and approval. AAU and APLU urge NIH to carefully think through the sequence of events in which investigators identify the IRB of record and the award is issued to prevent delaying the initiation of research.

Currently, the draft policy is light on the details related to implementation, such as how one defines a multi-site study, and definitions of responsibilities between the participating institutions. While this lack of detail may provide some welcome flexibility for some institutions, we are concerned that ambiguity may raise additional concerns, and we again strongly urge NIH to pay careful attention to comments submitted by institutions on this point. AAU and APLU appreciate the opportunity to provide some feedback on the draft NIH policy, and look forward to continuing to work with the agency as the final policy is developed.

Sincerely,



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President
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Peter McPherson
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