



January 28, 2015

Office of Clinical Research and Bioethics Policy
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892

Re: NOT-OD-15-026 (Comments on Draft NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research)

AcademyHealth, as the nonpartisan, professional home for more than 5,000 health services researchers, policy analysts, and practitioners, welcomes the opportunity to respond to the Office of Clinical Research and Bioethics Policy's request for comment on the Draft National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board (IRB) for Multi-Site Research.

Human subjects research protections are a moral compass critical to the public good. Health services researchers—from an array of disciplines ranging from outcomes research to health economics—are subject to the Common Rule, which ensures that the individuals who participate in health services research are protected, and that the data with which we work are collected, used, and stored ethically and appropriately. In revising its multi-site IRB policy, NIH will speed the initiation of studies by reducing administrative burdens that unnecessarily hinder scientific innovation and progress while assuring the rigorous and potentially enhanced protection of human subjects.

Utilization of a single IRB review of record for domestic sites of multi-site studies would undoubtedly reduce administrative burden and enhance the timeliness of research and represent a significant improvement to the current process, whereby the review processes and variations in determination associated with multi-site reviews can often delay for months even low-risk projects. However, the policy change is not without its political, administrative, and legal complexities. For instance, what criteria should be used to identify the single IRB in a multi-site study, e.g., principal investigator location, IRB specialty, reputation, or existing relationships with an IRB? Many protocols currently direct subjects to contact the institution's IRB with issues or questions. How do you address institutional accountability when there is a single IRB for a multi-site study? How does NIH address secondary consequences, such as how to allocate liability, and whether an appeals process is necessary? The draft policy itself does not directly address these questions, leaving much of these critical decisions to the investigators and institutions themselves.

Given the complexities, AcademyHealth encourages NIH to develop guidance and training for investigators and institutions on the implementation of the policy. Such guidance could be derived from the experiences of IRB systems that have already implemented more centralized IRB review processes, such as the National Cancer Institute Central Institutional

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Review Board, as well as the Veterans Health Administration's VA Central Institutional Review Board. Experiences and best practices from these and other centralized IRB systems would provide useful insights for NIH-funded investigators and institutions and facilitate the implementation of NIH's new policy.

AcademyHealth also encourages the Office of Clinical Research and Bioethics Policy to periodically assess the effectiveness of its single-site IRB policy to ensure that it does indeed streamline the research process and assure appropriate protections for human subjects. Such regular assessment would ensure the policy is responsive and flexible to evolving research needs and practice.

We support NIH's efforts to modernize its IRB policy while reducing the burden, delay, and ambiguity for investigators to produce valuable research. We hope that NIH's efforts spur continued dialogue on the conduct of research—such as long-awaited revisions to the Common Rule—that succeeds in further protecting human subjects rights and incentivizing innovative health care research.

Thank you for the opportunity to submit these comments. Should you have any questions, please contact me directly at 202.292.6700 or lisa.simpson@academyhealth.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa Simpson". The signature is fluid and cursive, with the first name "Lisa" and last name "Simpson" clearly distinguishable.

Lisa Simpson, M.B., B.Ch., M.P.H., F.A.A.P.

President and CEO
AcademyHealth