CYSTIC FIBROSIS FOUNDATION
ADDING TOMORROWS

January 29, 2015

Francis S. Collins, M.D., Ph.D.
Director
National Institutes of Health

Office of Clinical Research and Bioethics Policy
Office of Science Policy
National Institutes of Health
6705 Rockledge Drive, Suite 750
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Dear Dr. Collins:

The Cystic Fibrosis Foundation appreciates the opportunity to comment on the Draft NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research. We commend the National Institutes of Health (NIH) for publishing and seeking comment on a policy that is intended to produce efficiencies in the clinical trials process while still protecting research participants. At a time when research resources are restrained, efforts to reduce redundancy and improve efficiency in research should be considered if they can be implemented without risk to research participants.

Trials evaluating CF therapies are multi-site trials that can be slowed by repetitive review by local institutional review boards (IRBs). Our comments below reflect the experience of the Cystic Fibrosis Foundation and CF investigators who are engaged in multi-site review.

Consideration of Local Issues

In the draft policy, NIH identifies strategies for consideration of local issues by a central review board. The policy suggests that local issues and issues related to vulnerable populations might be addressed by the use of consultants or ad hoc members of the central review board with special knowledge of these issues. We are pleased that the policy acknowledges the need to address such issues, and we agree that there are opportunities within the central review structure for considering these matters.

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Exceptions to the Presumption of Central Review

The draft policy would permit exceptions to the general policy of central review. The policy states that "Exceptions will be allowed only if the designated single IRB is unable to meet the needs of specific populations or where local IRB review is required by federal, tribal, or state laws or regulations." As the draft policy is implemented through additional guidance and in grant and contract conditions, we recommend that the standards for permitting exceptions to central review be more specifically described.

Clarity about the standards for exceptions will help to ensure that exceptions are granted when central review is not adequate and will also protect against exceptions undermining the policy, which favors central review.

Respective Responsibilities of Central Review Board and Local Boards

According to the draft policy, the central review board will have responsibility for initial and continuing research review. The policy also states that, "All participating sites will be responsible for meeting other regulatory obligations, such as obtaining informed consent, overseeing the implementation of approved protocols, and, reporting unanticipated problems and adverse events to the single IRB of record." As the central review policy is implemented, we anticipate that additional clarification will be necessary regarding the "continuing research review" responsibilities of central review boards compared to the "other regulatory obligations" that will be retained by local boards. In order to avoid confusion and duplication of efforts, additional guidance related to ongoing oversight of studies and the respective responsibilities of the central and local review boards will be helpful.

We recommend that any additional guidance on this policy also address the liability concerns of research institutions. Some have voiced concerns about how liability issues will be addressed as they move toward utilization of single review boards.

NIH Leadership in Forming Central Review Boards

In the document outlining the draft policy on central review, NIH notes the successful experience with central review boards of the National Cancer Institute and the National Institute for Neurological Disorders and Stroke. As the NIH moves forward with a policy that encourages central review for NIH grantees, we urge the agency to consider undertaking additional efforts to convene and fund central review boards.

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We appreciate the opportunity to comment on the central review policy and commend NIH for advancing policies intended to bring efficiencies to the research process.

Sincerely,

Robert J. Beall, Ph.D.
President and Chief Executive Officer