CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

January 29, 2015

Francis S. Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Submitted by email at SingleIRBpolicy@mail.nih.gov

Dear Dr. Collins:

The undersigned organizations representing cancer patient, health professionals, and researchers appreciate 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 taking this step to reduce duplication and inefficiency in the initiation and oversight of multi-site research studies. This policy will provide appropriate protections for research participants while encouraging greater efficiency in initiation and oversight of research.

The National Cancer Institute (NCI) has been a leader in enhancing review of human subjects research, administering the NCI Central Institutional Review Board and fostering efficiencies in the review of multi-center clinical trials. Other institutes at NIH have also pioneered centralized review efforts. We are pleased that NIH is moving beyond these innovative efforts to set a standard for NIH-funded institutions to use a single institutional review board (IRB) of record for domestic sites of multi-site studies. A standard that applies to multi-site studies that are supported by NIH grants, contracts, or the NIH intramural program will begin to address the reluctance of many research institutions to utilize central IRBs. Whether the resistance to central review relates to institutional inertia, concerns about the management of local context, or concerns about regulatory liability in the case of non-compliance in a central review situation, the implementation of a clear NIH grant and contract policy will begin to address these reservations and concerns.

The draft policy provides for exceptions to the presumption that a single IRB will be used, if those exceptions are presented to NIH with appropriate justification. The draft policy states that, "Exceptions will be allowed only if the designated single IRB is unable

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to meet the needs of specific populations or where local IRB review is required by federal, tribal, or state laws or regulations." We anticipate that exceptions will be requested, perhaps somewhat routinely, by institutions asserting that local issues or the needs of specific populations can only be met by local IRB review. We urge NIH to develop clear policies for assessing local review issues or the needs of specific populations so that it can efficiently address requests for exceptions to single IRB review. Without clear standards for exceptions, the NIH policy favoring central IRB could be seriously undermined by the request for and grants of exceptions.

In the draft policy, NIH defines the responsibilities of the single IRB for a multi-site study and the responsibilities of individual sites. The draft policy notes 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." In the final policy, any additional guidance, and in the terms and conditions that are included in the Notice of Award or the requirements in the Contract Award, the respective responsibilities of the single IRB and the participating research sites should be reinforced. Because the single IRB policy represents a change in decades of research oversight and compliance practices, NIH should reinforce the new standards and provide clear guidance regarding implementation of the new standards.

In an era of restrained research resources, it is important that the research system embrace any opportunity to reduce duplication and enhance efficiency. We commend NIH for advancing a policy that encourages efficiency while still protecting those who participate in research.

We look forward to collaborating with NIH to publicize this new standard, when finalized, and to encourage research sites to adopt the use of a single IRB.

Sincerely,

Cancer Leadership Council

American Society of Clinical Oncology
Cancer*Care*
Coalition of Cancer Cooperative Groups
Fight Colorectal Cancer
Hematology/Oncology Pharmacy Association
Kidney Cancer Association
The Leukemia & Lymphoma Society
LIVE**STRONG** Foundation
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship

National Patient Advocate Foundation
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Prevent Cancer Foundation
Sarcoma Foundation of America
Us TOO International Prostate Cancer Education and Support Network