Subject: NIH Policy on the Use of Single Institutional Review Board for Multi-Site Research

Date: Thursday, June 29, 2017 at 3:17:13 PM Eastern Daylight Time

From: Research Administration

To: Research Administration

Attachments: image001.png

This is the first in a series of periodic updates about the NIH Single Institutional Review Board (sIRB) policy and its impact on Boston Children's Hospital (BCH) researchers.

For ***new, renewal, and resubmission applications due on or after January 25, 2018***, the National Institutes of Health (NIH) is requiring that all sites participating in multi-site studies involving non-exempt human subjects research use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46. *Please note that this requirement was initially set for September 2017, but has recently been extended.* While the policy is intended to streamline the IRB review process, reduce inefficiencies, and expedite research without compromising ethical principles and/or the protection of human research study participants, it does create additional administrative responsibilities and costs for the site serving as the sIRB. BCH is evaluating these costs and will provide more detailed information in a future update.

Boston Children's Hospital IRB is willing to serve as the sIRB for NIH submissions. If you are planning to submit or participate in an application proposing a multi-site research project and would like BCH to serve as the sIRB, please contact Daniel Alderson, IRB Reliance Specialist, @ daniel.alderson@childrens.harvard.edu to discuss your project, its needs, and to determine the costs required to establish and review protocols for multiple study sites. These are allowable and allocable direct costs and should be included in your NIH budgets.

Who Does the Policy Apply to?

- Domestic applicants, awardees and participating domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research supported by grants ("R" or "P") cooperative agreements ("U"), contracts, or the NIH Intramural Research Program. (*Ongoing projects are not expected to follow the policy until a competing renewal application is submitted, at which time transition to a single IRB must be implemented.*)

Who Is Exempt from this Policy?

- Career development ("K"), research training ("T"), or fellowship ("F") applicants and awardees.
- Foreign sites participating in NIH-funded, multi-site studies.
- Multi-site studies involving research classified as 'Exempt' from the BCH IRB office.

Are there Exceptions to the Policy?

NIH will consider exceptions to the policy where the review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy. Requests for exceptions must be based on legal, regulatory, or policy requirements or if there is a compelling justification. It is recommended you contact the IRB office to discuss if you think you need to request an exemption.

My NIH Application is due before January 25, 2018, May I Propose BCH as the sIRB?

Yes. Please contact Daniel Alderson **as soon as possible**. Because the application is due before the NIH mandate, sIRB application requirements will not yet be in effect. BCH suggests that, at minimum, applicants include the costs of having BCH serve as the sIRB in their NIH budgets and detailed in their budget justifications. Applicants should emphasize how the use of an sIRB will benefit their proposed projects. Additionally, applicants may also want to include signed letters from each participating site's IRB endorsing the selection of BCH as the sIRB.

Where Can I Find More Information about the NIH Policy?

- Final Policy on the Use of Single Institutional Review Board for Multi-Site Research: NOT-OD-16-094, NOT-OD-17-027, and NOT-OD-17-076.

Research Administration
Boston Children's Hospital
617-919-4664
resadmin@childrens.harvard.edu