Human Subjects Protection Update (Special Communication) July 2016

IRB (Institutional Review Board) *Boston Children's Hospital*

NIH Policy on the Use of a Single IRB for Multi-site Research

On June 21st, the National Institutes of Health (NIH) published the "Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research" (https://www.federalregister.gov/articles/2016/06/21/2016-14513/final-nih-policy-on-the-use-of-a-single-institutional-review-board-for-multi-site-research).

Effective May 25, 2017, all domestic sites participating in a NIH-funded multi-site research study are required to use a single IRB rather than obtaining local IRB approval from each individual site. This policy will be applicable to sites conducting the same non-exempt human subjects research protocol supported through NIH grants, cooperative agreements, contracts, or the NIH Intramural Research Program. However, the policy does not apply to NIH career development, research training or fellowship awards. It will apply to all competing grant applications (new, renewal, revision or resubmission) received on or after May 25, 2017.

Boston Children's Hospital IRB already utilizes single IRB models and reliance agreements for many multi-site research studies. We have extensive experience serving as both the Reviewing/Lead single IRB for multiple sites as well as relying on another IRB. Boston Children's Hospital IRB maintains current policies, procedures and resources needed to not only comply with NIH's upcoming mandate, but to continue to serve as a leader in single IRB review models particularly in pediatric research. We have anticipated this trend toward single IRB and reliance agreement use and are ready for the required change. See our 'Reliance Agreements' webpage (http://www.childrenshospital.org/research-and-innovation/research/research-administration/office-of-clinical-investigation/reliance-agreements) for current guidance on Boston Children's use of single IRBs.

However, this policy will require increased responsibilities for investigators and new types of decision making regarding multicenter grants. Investigators will be tasked with proposing which institution will serve as the single IRB, budgeting costs of single IRB use and working with all involved institutions to ensure infrastructure and resources are in place for utilizing and maintaining a single IRB model for the multi-site research study.

The NIH has provided some information and documentation regarding this upcoming requirement (http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/models-irb-review) and indicated future guidance on topics such as associated costs, considerations on selecting the single IRB, content of the single IRB plan needed in application submissions, investigator and institutional roles/responsibilities and the process for exceptions.

The Office of Sponsored Programs (OSP) will be distributing updated guidance documents (including application checklists) to reflect these new requirements for grant submissions involving the use of a single IRB. The NIH Office of Science Policy in consultation with the Office of Policy for Extramural Research Administration in the NIH Office of Extramural Research and the Division of Financial Advisory Services, OM, has also provided guidance on the Use of a Single Institutional Review Board for Multi-Site Research and which of those

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activities should generally be charged as Facilities and Administrative (F&A) costs (also called indirect costs) and which may be charged as direct costs. Investigators interested in proposing that Boston Children's Hospital serve as the single IRB are encouraged to contact IRB Specialist Daniel Alderson so that charge issues may be addressed in the grant. We will provide more information about this in the future. More detailed information may be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-109.html

Please note at this time the mandated use of a single IRB for multi-site research studies is specific to NIH-funded research, however a current Notice of Proposed Rulemaking (NPRM) within the U.S. Department of Health & Human Services has proposed a similar mandate (http://www.hhs.gov/ohrp/regulations-and-policy/regulations/nprm-home/index.html) for all federally funded research studies. Boston Children's Hospital IRB will keep the research community advised should a new rule be issued.

We will be providing further information and upcoming presentations to educate the Boston Children's Hospital research community as more guidance is issued about single IRB review. For additional information and to request presentations for your department, please contact IRB Specialist Daniel Alderson at daniel.alderson@childrens.harvard.edu or 617-919-1918.

The Institutional Review Board (IRB) has been established to oversee the protection of human research subjects at Boston Children's Hospital. Boston Children's Hospital is committed to safeguard the rights and welfare of all children, adolescents, adults and family members who volunteer to participate in research. To this end, the Institutional Review Board upholds the principles of the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research, as the cornerstone of our mission, organization and daily activities.

- Have questions or comments about any of the articles in this newsletter?
- Need advice about your research?
- Want to know more about human subjects protection at Boston Children's Hospital?

Please don't hesitate to contact the IRB and one of our staff will be happy to assist you.