



Additional Human Subject Protection Reviews

Policy

Certain research protocols require additional reviews as part of the human subject protection program at Boston Children's Hospital. These reviews are referred to as ancillary reviews. In some situations review and approval by an ancillary reviewer is required before final approval may be released. These are reviews that are considered a component of the human subject research protection program. The mandated reviews and approvals are marked by an asterisk*. The other ancillary reviewers are notified about the upcoming research but their approval is not required. They are notified for informational purposes so that the ancillary reviewer can contact them to obtain more information about coordinating the research as necessary. The following additional reviews may occur, as applicable to the research.

- Department Chairs/Chiefs*
- Scientific Review*
- Clinical Translational Research Unit*
- Radiation Safety Committee*
- General Counsel and Conflict of Interest*
- Radiology
- Laser Committee*
- Institutional Biosafety Committee (IBC)*
- Medical Intensive Care Unit*
- Neonatology*
- Pharmacy
- Clinical Trials Business office*
- Nursing
- Social Work
- Regulatory Affairs*
- Biomedical Engineering
- HIPAA Privacy Officer

Purpose

To adequately protect human subjects, Boston Children's Hospital requires an integrated and interdisciplinary review of human subject research protocols. The IRB administrative office is responsible for assuring that the appropriate reviews take place prior to releasing final approval. In addition to the specific additional reviews listed below, the Director of Clinical Research Compliance, the Chairperson, and the IRB have the ability to request that any additional reviews they deem necessary occur as part of the review and approval process.

Procedures

Pre-Consultation on a Protocol Prior to Submission

Any staff member planning a research project that involves human subjects may discuss the project with the staff of the Institutional Review Board prior to submission. Investigators are encouraged to use this resource to assist them in developing the protocol application. Staff of the Institutional Review Board is available to review protocols and consents before submission to the Committee to provide preliminary comments and suggest modifications.

If a project involves participation of staff nurses, the services of the pharmacy, a heavily used area in the hospital (i.e., Emergency room), or another division's patients, investigators must contact appropriate staff and discuss necessary arrangements before the protocol is submitted. Even when a protocol is approved, the conduct of research is contingent upon the protocol's feasibility.

Reviews Required Prior to Submission to IRB

Before a protocol is accepted for review by the IRB, specific signatures are required. They are as follows:

Principal Investigator: The application must be submitted directly by the principal investigator. There may be only one principal investigator for a protocol.

Department/Division Chief: The application must be endorsed and approved by the Department Chair or Division Chief (if the investigator is a member of the Department of Medicine).. If the Department Chair or Division Chief has designated another individual to sign in his or her absence, this is permitted. **Department/Division Chief must occur prior to IRB review.**

Scientific Review: Each department and division is required to have an individual approve the protocol for its scientific merit. Each Chair or Chief has designated an individual(s) who is authorized to sign. A list of these individuals is maintained by the Quality Improvement Office and is available to all investigators on the Office of Clinical Investigation web site. If the protocol is multidisciplinary, one department/division may designate another for Purposes of scientific review. The process of scientific review is described in another policy. Scientific review must be obtained prior to IRB submission.

CTSU: All protocols to be conducted on the CTSU or that require resources of the CTSU must be reviewed by the CTSU Review Committee before submission to the Institutional Review Board. The protocol application also contains information required by the CTSU or their review.

Other Ancillary Reviews Required

Radiation Safety Committee: The Institutional Review Board will not approve any protocol that involves administration of radioactive agents or radiation exposure (outside of clinical care) until the approval of the Radiation Safety Committee and/or the Radioactive Drug Research Committee has been given. When protocols are submitted that involve

radiation safety review, a copy is forwarded to the Radiation Safety Committee. Final approval will not be released by the IRB Office until approval by the Radiation Safety Committee is obtained.

Clinical Trials Business Office/Clinical Trial Agreements: Any research intended to support regulatory approval of a product and/or sponsored by a nongovernmental, for-profit entity requires a clinical trial agreement between Boston Children's Hospital and the sponsor. Sponsorship may be in the form of providing money, drugs, devices, biologics, or software. If a clinical trial agreement is necessary, notification of approval by the Committee will be released only after a clinical trial agreement is signed. Agreements are negotiated by members of the clinical trials business office. These individuals will negotiate and establish the terms of the agreement and will review the clinical trial. The IRB staff are contacted if there are any questions or concerns about human subject protection issues as they relate to the clinical trial agreement. Once the agreement is signed, the IRB staff will be notified through the electronic protocol system. There are administrative review fees for industry sponsored trials. Final approval notifications and consent documents will not be released by the IRB administrative staff until they are notified in writing that a clinical trial agreement has been signed.

Any research protocol that generates patient care charges must also be reviewed and signed off by the Clinical Trials Business office. This process is used to determine who will pay for which patient related charges and to set up the appropriate budget and arrangements so that appropriate billing may occur. Approval of protocols may not be released until there is notification this process is complete.

Institutional Biosafety Committee (IBC): Any protocol that involves human gene transfer, vaccine studies that contain biological material with recombinant or synthetic nucleic acid molecules, xenotransplants, xenografts, or therapeutic approaches that involve treating human subjects with biological agents requires review and approval by IBC prior to the release of final approval by the Institutional Review Board. Information regarding the IBC review is provided to the Institutional Review Board for consideration during review. Final approval will not be released until the IBC approval is obtained.

Department of Radiology: Any protocol that involves the use of radiology is forwarded to the Manager of Radiology. Formal approval from Radiology is not required. However, the Department of Radiology is alerted that their services are required and they may contact the investigator regarding questions or concerns.

Laser Committee: Any protocol which uses lasers (approved or investigational devices) for research related procedures must be reviewed and approval by the Laser Safety Committee prior to final release of protocol approval.

Neonatal Populations: If the study involves 7 North (Neonatal Intensive Care Unit), the protocol requires the signature of the NICU Chief. Any protocol that involves a neonatal population (including the newborn nurseries), must be submitted to the Neonatology Scientific Review Committee.

Pharmacy; Any protocol that involves the use of a pharmaceutical agent is reviewed by the Investigational Drug Pharmacist The pharmacist is also present at all IRB meetings to present and issues of concerns and may also choose to contact the investigator directly.

Regulatory Affairs; All protocols that include the use of drugs or devices outside the clinically indicated labeling are referred to the Director of regulatory affairs to determine if an IND or IDE is required .This may occur when the protocol is submitted or during the review process . Recommendations as to whether a device may be considered exempt or meet criteria for a Non-Significant Risk determination will be forwarded to the IRB staff and IRB as necessary. Once any determination is made by regulatory affairs the

information will be provided back to the IRB, if an IND or IDE is required, the IRB approval will not release approval until they receive notification that it is obtained. The IRB will require a copy of the letter form the FDA as appropriate documentation. If there is any question as to whether it is required the regulatory affairs specialist will consider asking for a letter of exemption, if appropriate and this will be provided to the IRB as well.

Medical Intensive Care Units: Research that is conducted in the intensive care units requires approval by the Directors or their designee. This approval assures the research is well coordinated and prioritized in accordance with the clinical care provided in the intensive care units.

Related Content

Document Attributes

Title	Additional Human Subject Protection Reviews		
Author	Susan Kornetsky	Dates Reviewed/ Revised	04/01/05
Reviewed/ Revised by	Susan Kornetsky	Dates Reviewed/ Revised	05/04/07 07/17/07 03/19/2010
Copyright	©Boston Children’s Hospital, 2015	Last Modified	5/1/15
Approved	<div style="border-bottom: 1px solid black; padding-bottom: 5px;"> Susan Kornetsky, MPH Director of Clinical Research Compliance </div> <div style="border-bottom: 1px solid black; padding-bottom: 5px;"> August Cervini, MBA Vice President for Research Administration </div>		