Ancillary Review: Additional Human Subject Protection Reviews

Purpose

This policy identifies Boston Children's Hospital's departments that provide ancillary review and describes the procedures.

Policy

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 ancillary reviews take place prior to releasing final approval.

In addition to the specific additional reviews listed below, the Director of Clinical Research Compliance, the IRB Chairperson, and the IRB can request that any additional reviews they deem necessary occur as part of the review and approval process. These reviews are referred to as ancillary reviews.

Mandated Ancillary Review

In some situations, review and approval by an ancillary reviewer is required before final approval may be released. Mandated Reviews are the following:

Required Reviews Prior to Submitting to the IRB:

- Department Chairs/Chiefs
- Scientific Review
- ICCTR

Other Required Reviews:

- Clinical Trials Business Office/ Clinical Trial Agreements
- CT.GOV Review
- General Counsel and Conflict of Interest
- Information Technology/Security
- Institutional Biosafety Committee (IBC)
- Intensive Care Units
- Laser Committee
- Neonatology
- Pathology
- Radiation Safety Committee/Radioactive Drug Research Committee
- Regulatory Affairs
- Research Information Technology/Security

Other Ancillary Reviews

Other ancillary reviews are notified about the upcoming research, but their approval is not required. These reviews are notified for informational purposes so that the ancillary reviewer can contact the researcher to obtain more information about coordination of the research.

- Biomedical Engineering
- HIPAA/GDPR Privacy Officer
- Nursing
- Pharmacy
- Department of Radiology
- Social Work

Procedures

Pre-Consultation on a Protocol Prior to Submission

Any Boston Children's Hospital staff member planning a research project that involves human subjects may discuss the project with the Institutional Review Board (IRB) administrative staff prior to submission. IRB administrative staff are available to review protocols before submission to the Committee to provide preliminary comments and suggest revisions. They will also be able to advise researchers about ancillary reviews. Investigators are encouraged to use this resource to assist them in developing the protocol application.

Feasibility

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 approvals are required. They are as follows:

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 their absence, this is permitted.

Scientific Review: Each department and division are 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 available to all investigators on the IRB web site.

- If the protocol is multidisciplinary, one department/division may designate another for purposes of scientific review. For further information see IRB policy, ***Department/Division Scientific Review of Human Subject Research***.

- All protocols that involve Gene and Cell Therapy must be reviewed by a Committee with specialized expertise. This review replaces the scientific review by the investigator's department/division

ICCTR (Institutional Centers for Clinical and Translational Research: All protocols supported by the ICCTR must be reviewed by the ICCTR Review Committee before submission to the IRB.

Required Ancillary Reviews

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 IRB 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 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.

CT.GOV Review: All protocols are reviewed by the CT.gov specialist to determine if registration and reporting of results is required**.**

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 IRB. Information regarding the IBC review is provided to the IRB for consideration during review.

Intensive Care Units: Research that is conducted in the Intensive Care Units require 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**.**

Laser Safety 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.

Neonatology: If the study involves 7 North: Neonatal Intensive Care Unit (NICU), 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.

Radiation Safety Committee/Radioactive Drug Research Committee: The IRB 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.

Regulatory Affairs: All protocols that include the use of drugs, devices, biologics and potential medical apps and software are referred to a Regulatory Affairs Specialist to assure that all FDA regulations are followed as applicable**.** 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 administrative 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 will not release approval until they receive notification that it is obtained.

The IRB will require a copy of the letter from 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.

Research Information Technology/Security: All protocol applications contain a series of questions that ask about IT technology, data sharing, use of apps, use of social media, and wearable devices. Based on pre-specified criteria, protocols may be sent for a research information technology review to confirm the research follows institutional policies for security, technology, data sharing, and privacy.

Other Ancillary Reviews

Biomedical Engineering: Protocols that involve the use of devices that fall under the oversight of the biomedical engineering department (i.e. investigational devices that utilize electricity) will be sent to this group so they may contact the investigator and provide the necessary safety checks,

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.

HIPAA/GDPR Privacy Officer: The Privacy Officer is contacted when beaches of HIPPA are reported, so that the incident may undergo a risk analysis and corrective actions coordinated with the IRB. Protocols that are impacted by the GDPR regulations will be forwarded to the Privacy Officer for evaluation and may impact the informed consent process.

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.

Social Work: Protocols that involve the use of assessments that may prompt the need for emergency social worker evaluation/intervention (i.e. suicidality or immediate harm to oneself or other) are sent to the Social Work Department to determine that appropriate resources are available.

Related Content

IRB Policy

Department/Division Scientific Review of Human Subject Research.

Document Attributes

Title	**Ancillary Review: Additional Human Subject Protection Reviews**		
Author	Susan Kornetsky	**Dates Reviewed/ Revised**	4/1/2005 5/04/2007 7/17/2007 3/19/2010 5/1/2015 10/26/2019
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