Status Active PolicyStat ID 17410560

Boston Children's Hospital

Where the world comes for answers

Effective 3/1/2025

Next Review 2/29/2028

Owner Susan Kornetsky: Manager

Department Research

Applicability Boston Children's Hospital- Policies & Procedures

Ancillary Review: Additional Human Subject Protection Reviews Policy/Procedure

Internal Approval

SVP, Research Administration

EVP, Chief Scientific Officer

Scope

This policy applies to the Boston Children's Hospital (BCH) Research department and the respective staff.

Definitions

Ancillary Reviews are reviews of human research projects by compliance groups, departments, or individuals and happen in addition to the IRB review. These reviews vary, depending on the funding requirements, type of research performed and hospital resources utilized and some may be required by federal or state regulations, IRB policy, or institutional requirements.

Policy Statements

This policy identifies ancillary review requirements and workflow process. This policy is applicable to all human research projects reviewed by the BCH IRB or an external IRB. Ancillary reviews for all cancer related human projects conducted under the Dana-Farber/Harvard Cancer Center (DF/HCC) National Cancer Institute (NCI) Cancer Center Support Grant (CCSG) follow the DF/HCC specific requirements and workflow.

Ancillary reviews allow individuals, departments, offices, and other additional reviewers to give feedback,

approval, and/or provide documentation on the submission in parallel with the IRB review process. Not all studies require ancillary review.

Ancillary Review Workflow

1. The IRB system automatically routes submissions requiring an ancillary review to the appropriate departments or committees for approval at the time the protocol is assigned for IRB review.
2. The IRB system routes ancillary reviews based on PI responses to questions in the application.
3. IRB analysts may manually trigger ancillary reviews during the administrative pre-review or IRB review process as needed.
4. Ancillary reviewers receive a system notification when the review is assigned.
5. Ancillary reviewers can use the Submit Ancillary Review activity to document completion.

Required Ancillary Reviews

Required ancillary reviews assists the IRB with matters related to research feasibility, risk, regulatory requirements and research compliance. All required ancillaries assigned automatically or manually triggered by IRB office, must be complete before release of IRB approval. Completion of the following ancillary reviews are required to secure IRB approval:

1. Clinical Trial Agreements Office: Streamlines and centralizes the workflows in preparing an Industry Sponsored clinical trial contract and budget, as well as other clinical research contracts managed by CR Finance and CR Agreement groups. Verifies a number of things that include but are not limited to whether an agreement is in place that includes appropriate terms, conditions, and disclosures to adequately protect and inform human subjects.
2. ClinicalTrials.gov Review: Reviews by the CT.gov specialist to determine if registration and reporting of results is required.
3. General Counsel, Conflict of Interest Review: Evaluates all disclosed conflict of interests in accordance with institutional policies,
4. HIPAA: Reviews conducted by the Privacy Office related to privacy and confidentiality. .
5. Information Technology/Security: All protocol applications contain a series of questions that ask about IT, 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.
6. 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.
7. 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.

8. 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.
9. MRI: Review conducted for all research which involves MRI equipment/scans for research purposes.
10. Neonatology: If the study involves 7 North: Neonatal Intensive Care Unit (NICU), the protocol requires the signature of the NICU Chief.
11. Pathology: Review conducted for the collection of tissue removed for clinical purposes that would routinely go to pathology
12. Pharmacy: Any protocol that involves the use of a pharmaceutical agent is reviewed by the Investigational Drug Pharmacist.
13. Radiation Safety Committee/Radioactive Drug Research Committee: Any protocol that involves administration of radioactive agents or radiation exposure (outside of clinical care) requires review by Radiation Safety Committee and/or the Radioactive Drug Research Committee.
14. Drug/Device, 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 U.S. Food & Drug Administration (FDA) regulations are followed as applicable.
15. EQuIP (Education and Quality Improvement Program): Ensures all new/transfer PI for any protocol that intervenes or interacts with research subjects completes orientation New PI training with a member of the Education and Quality Improvement Program (EQuIP) staff.
16. Office of Health Equity and Inclusion (OHEI): Review required for research with a specific objective related to EDI to ensure research is aligned with the BCH Declaration on Equity, Diversity and Inclusivity.

Not Required 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.
- These ancillary reviews are automatically routed based on PI response to the application; however, ancillary reviewers do not have to use the Submit Ancillary Review activity to document completion.
- Examples of not required ancilarry reviews include, but are not limited to:
    - Radiology
    - Biomedical Engineering
    - Social work
    - Nursing

Related Content

- CRO Policy: Scientific Review

Approval Signatures

Step Description	Approver	Date
Co-chair Approval	David Davis	3/1/2025
Site Administrator: Education/ Training Requirement	Dwight Mayfield	2/25/2025
Steering Committee	Dwight Mayfield	2/25/2025
Required Departmental Review/Approval	August Cervini	1/17/2025
Committee Chair(s)	Susan Kornetsky: Manager	1/17/2025
Contributor(s)	Susan Kornetsky: Manager	1/17/2025
Document Owner	Susan Kornetsky: Manager	1/17/2025

Applicability

Boston Children's Hospital- Policies & Procedures