Additional Human Subject Protection Reviews

Policy

Certain research protocols require additional reviews as part of the human subject protection program at Children's Hospital. The following additional reviews may occur, as applicable to the research.

- Department Chairs/Chiefs
- Medical Staff Executive Committee
- Scientific Review
- Clinical translational Research Unit
- Radiation Safety Committee
- Radiology
- Laser Committee
- Committee on Microbiological Safety
- Medical Intensive Care Unit
- Neonatology
- Corporate Sponsored Research
- Clinical Trials office
- Nursing

Purpose

To adequately protect human subjects, Children's Hospital requires an integrated and interdisciplinary review of human subject research protocols. The Clinical Investigation 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 CCI 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 Committee on Clinical Investigation prior to submission. Investigators are encouraged to use this resource to assist them in developing the protocol application. Staff of the Committee on Clinical Investigation 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 signed by the principal investigator. There may be only one principal investigator for a protocol. An original signature is required.

Department/Division Chief: The application must be endorsed and signed by the Department Chair or Division Chief (if the investigator is a member of the Department of Medicine). An original signature is required. If the Department Chair or Division Chief is not available and he or she has designated another individual to sign in his or her absence, this is permitted.

Scientific Review: Each department and division is required to have an individual sign 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 Committee on Clinical Investigation. The protocol application also contains information required by the CTSU or their review.

Other Ancillary Reviews Required

Radiation Safety Committee: The Committee on Clinical Investigation 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 Clinical Investigation Office until approval by the Radiation Safety Committee is obtained.

Clinical Trials 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 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 the Manager of Corporate Funding. This individual will negotiate and establish the terms of the agreement and will review the clinical trial. The Director of Clinical Research Compliance is 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 will be notified in

writing. There is a one time $2,000 administrative review fee for industry sponsored trials. Final approval notifications and consent documents will not be released by the Clinical Investigation Office 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 be reviewed and signed off by the Clinical Trials 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

Committee on Microbiological Safety (COMS): Any protocol that involves human gene transfer, xenotransplants, xenografts, or therapeutic approaches that involve treating human subjects with infectious agents requires review and approval by COMS prior to the release of final approval by the Committee on Clinical Investigation. Information regarding the COMS' review is provided to the Committee on Clinical Investigation for consideration during review. Final approval will not be released until COMS 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; If at any time before or during the review process there is a question as to whether an IND or IDE is required for a protocol, the protocol is referred to regulatory affairs for an assessment. Once a determination is made the information will be provided back to the IRB, if an IND or IDE is required, the IRB approval will not released 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.

Related Content

None identified.

Document Attributes

Title	Additional Human Subject Protection Reviews		
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