



Medical Record and Database Review Requests

Policy

- All retrospective medical record reviews and database requests that are performed for research purposes require review by the Institutional Review Board (IRB).
- A specialized protocol application has been developed for retrospective medical record review and database requests for research purposes. The form requests the following information: who will perform the review; the purpose of the review; who will have access to the information; what the information will be used for; and the steps that will be taken to protect confidentiality. Information that is required to assure compliance with HIPAA regulations is also requested. In addition, the form requests the information needed to determine whether activity constitutes research with human subjects, whether it may be exempt from review or whether expedited review is required. Information is also collected to determine whether informed consent requirements may be waived under 45 CFR 46.116(d) or 45 CFR 46.117.

Purpose

To identify the medical record reviews and database requests that are subject to IRB review, and to provide guidelines for the conduct of this review.

Procedures

1. Boston Children's Hospital has in place a simplified IRB review process for research that involves only the retrospective collection of data from medical records, computer databases, radiographs, and any other hospital-based records that exist for purposes other than research (e.g., quality improvement records). The general term "records" will be used. This form may also be used when investigators are obtaining records from other institutions for analysis purposes.
2. The required IRB review applies to all research-related record reviews and database requests for research, regardless of whether the investigator wishes to maintain an identifier or a link to an identifier.
3. If a protocol involves interaction with a subject, requires informed consent or requests information from physicians outside of Boston Children's Hospital, a full IRB protocol application is required. If the research involves only the retrospective review of information contained in record, or computer database, a specialized form may be completed. Because X-rays and radiograph films are considered a part of the medical record, the same procedures apply.
4. Investigators are asked to submit the special Record review application form to the IRB for review and approval. This form is part of the electronic protocol review system.

5. The type of information required for review includes where and how the data will be stored, who will have access to it, who is responsible for maintaining it, and the steps taken to maintain confidentiality will be considered.
6. The Director of Clinical Research Compliance, Assistant Director or IRB analyst reviews the form and clarifies any questions or concerns with the investigator. A determination is made as to whether the activity constitutes human subject research, whether the activity is exempt or whether expedited review is appropriate. If the activity is determined to be expeditable, the Director of Clinical Research Compliance, Assistant Director or IRB analyst, as voting members of the IRB, may approve the request.
7. Once approved or a determination made, the Director of Clinical Research Compliance, Assistant Director or IRB analyst notify the investigator. The notification indicates whether the request was determined to be non-human subject research, exempt or expedited. Non-human subject research will not require any additional follow-up. Exemptions will follow the policy and procedures for "Exemptions".
8. For those activities that are determined to be expeditable, approval is valid for one year period. Investigators are sent notification prior to expiration and are asked to complete a continuing review form if the research is to continue. These forms are reviewed and approved by the Director of Clinical Research Compliance, Assistant Director or IRB analyst.

Related Content

Document Attributes

Title	Medical Records and Database review requests		
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