



Excess/Discarded Human Biological Specimen Use

Policy

- All requests to use excess/discarded human biological specimens for research purposes require review by the Institutional Review Board (IRB). Biological specimens is defined as any specimen obtained from patients (or human research subjects), e.g.: fixed, frozen or fresh pathology specimens, any blood, urine, saliva, semen, breast milk or other biological material, any purified DNA, RNA, proteins, cell lines or clones.
- A specialized protocol application has been developed for excess/discarded human biological specimen review. The form requests the following information: who will obtain the specimens and have access to it, the purpose of the specimen use, 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

This policy describes the content and conduct of IRB review of requests to excess/discarded use human biological specimens for research purposes.

Procedures

1. Boston Children's Hospital may review research that involves only the use excess/discarded human biological specimens for research purposes under expedited review procedures if it falls within the regulatory criteria for expedited review. The IRB administrative office may also determine it is exempt or does not constitute the criteria for human subject research.
2. The required IRB review applies to all use of excess/discarded human biological specimens for research purposes 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 or requires informed consent, a full IRB protocol application is required.
4. Investigators are asked to submit the protocol application to the IRB office through the electronic submission process review and approval.
5. The IRB also considers the type of information under review, 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.

6. The Director of Clinical Research Compliance, the Assistant Director or the IRB analysts reviews the form and clarifies any questions or required clarifications 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 has been determined to be expeditable it is approved by the Director of Clinical Research Compliance, Assistant Director or IRB analyst, as voting members of the IRB and authorized to perform the expedited review.
7. Once review is complete, the investigator is notified. 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 a one – year period. Investigators are sent notifications prior to expiration and are asked to complete a continuing review form if the work is to continue. The Director of Clinical Research Compliance, Assistant Director or IRB analyst review and approve the continuing reviews.

Related Content

Document Attributes

Title	Excess/Discarded Human Biological Specimen Use		
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