Excess/Discarded Human Biological Specimen Use

Policy

- All requests to use excess/discarded human biological specimens for research purposes require review by the Committee on Clinical Investigation (CCI). 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 CCI review of requests to excess/discarded use human biological specimens for research purposes.

Procedures

1. 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 CCI may also determine it is exempt or does not constitute the criteria for human subject research.
2. The required CCI 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 CCI protocol application is required.
4. Investigators are asked to submit the protocol application to the Clinical Investigation Office for review and approval.

5. The CCI 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 or Manager reviews the form and clarifies any remaining issues with the investigator. A determination is made by the Direct of Clinical Research Compliance or Manager 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, the Director of Clinical Research Compliance or Manager, as voting members of the IRB are authorized to perform the expedited review.
7. Once review is complete, the request is approved by the Director of Clinical Research Compliance or Manager , and 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 one –year period. Investigators are sent notification two months prior to expiration and are asked to complete a continuing review form if the work is to continue. The Director of Clinical Research Compliance or Manger review and approve the continuing reviews

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Related Content

Document Attributes

Title	Excess/Discarded Human Biological Specimen Use		
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