

Institutional Review Board (IRB) Policies & Procedures Manual



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Secondary Use of Human Biological Specimen and Data

Purpose

This policy describes the content and conduct of IRB review of requests for secondary use of human biological tissue and data for research purposes.

Policy

All requests for secondary use human biological specimens/data for research purposes require review by the Institutional Review Board (IRB) administrative office for a determination as to whether the use constitutes non-human subject research or whether it needs to be classified as exempt or require expedited or full committee review.

Human Biological specimens are defined as any specimen obtained from patients (or human research subjects), i.e. fixed, frozen or fresh pathology specimens, 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 secondary use of human biological specimen/data review. The form requests the following information:

- Type of data/specimen
- How it was acquired
- The presence of identifiers or link to identifiers
- Who will obtain the specimens/data and have access?
- The purpose of the specimen/data use
- What the information will be used for
- The steps that will be taken to protect privacy confidentiality
- Information about data/specimen storage
- Use and transfer.
- Information that is required to assure compliance with HIPAA regulations is also requested.

Procedure

1. Boston Children's Hospital may review research that involves only the secondary use human biological specimens/data to determine if it:
 - a. meets the criteria for human subject research
 - b. may be considered exempt including the need for limited review when applicable
 - c. may require review under expedited review procedures or full committee review.
2. If a protocol involves interaction with a subject a full research protocol is required.

3. Investigators are asked to submit the **Secondary Use Human Biological Specimens/Data** forms to the IRB office through the electronic submission process review and approval.
4. The Director of Clinical Research Compliance, the Assistant Director, or the IRB analyst reviews the form and clarifies any questions with the investigator.
5. The Director of Clinical Research Compliance, the Assistant Director and the IRB analysts (IRB Administrative Office) are all IRB members, and are allowed to make non-human subject determinations.
6. As IRB members, the IRB Administrative Office are also allowed to make human subject research activity determinations. If it is human subject research, then it will be determined if it is:
 - a. Exempt, and if limited review is required, or
 - b. Expedited. For research that undergoes expedited review, the form requests:
 - i. information to determine whether informed consent requirements may be waived under 45 CFR 46.116(f) or 45 CFR 46.117(c)1. and
 - ii. whether a waiver of HIPAA authorization may be granted.
 - c. If the IRB Administrative Office requires further support, the IRB Chairs can be contacted, or the protocol can be reviewed by the full committee.
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.
8. Non-human subject research will not require any additional follow-up.
9. Exemptions will follow the IRB policy: **Exemptions**.
10. For those activities that undergo expedited review, an Administrative Update will be required in a 1-year period. Expedited protocols will follow the IRB policies: **Expedited Review and Continuing Review and Administrative Update**.

Related Content

IRB Policy

Continuing Review and Administrative Update

Exemptions

Expedited Review

IRB Form

Secondary Use human Biological Specimens/Data

Document Attributes

Title	Secondary Use of Human Biological Specimen and Data		
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