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Owner	Susan Kornetsky: Manager
Department	Research
Applicability	Boston Children's Hospital- Policies & Procedures

Secondary Use of Human Biological Specimen and Data Policy/Procedure

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Internal Approval

SVP, Research Administration

EVP, Chief Scientific Officer

Scope

This policy applies to the Boston Children's Hospital (BCH) Research department and the respective staff.

Definitions

Human biological specimens: Any specimen obtained from patients (or human research subjects), e.g. 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.

Policy Statements

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

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.

Boston Children's Hospital IRB may review research that involves only the secondary use human

biological specimens/data to determine if it:

1. Meets the criteria for human subject research
2. May be considered exempt including the need for limited review when applicable
3. May require review under expedited review procedures or full committee review.
4. If a protocol involves interaction with a subject, a full research protocol is required.

Procedures

A specialized protocol application has been developed for secondary use of human biological specimen/data review. The form requests the following information:

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

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Protocol Submission and Review

1. 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.
2. The Senior Director of Clinical Research Compliance, the Director, or an IRB analyst reviews the form and clarifies any questions with the investigator.
3. The Senior Director of Clinical Research Compliance, the Director and the IRB analysts (IRB Administrative Office) are all IRB members and are allowed to make non-human subject determinations.
    a. IRB members are allowed to make human subject research activity determinations. If it is human subject research, then it will be determined if it is:
        i. Exempt, and if limited review is required, or
        ii. Expedited. For research that undergoes expedited review, the form requests:
            1. Information to determine whether informed consent requirements may be waived under 45 CFR 46.116(f) or 45 CFR 46.117(c)1. and
            2. Whether a waiver of HIPAA authorization may be granted.

b. If the IRB Administrative Office requires further support, the IRB Chairs can be contacted, or the protocol can be reviewed by the convened IRB.

4. 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.
    a. Non-human subject research will not require any additional follow-up.
    b. Exemptions will follow the IRB policy: *Exemptions*
    c. 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

- Department of Health and Human Services Regulations
    - 45 CFR 46.116(f): General waiver or alteration of consent
    - 45 CFR 46.117(c): Documentation of informed consent
- IRB Policies
    - *Continuing Review and Administrative Update*
    - *Exemptions*
    - *Expedited Review*
- *IRB Form: Secondary Use Human Biological Specimens/Data*

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Approval Signatures

Step Description	Approver	Date
Co-chair Approval	David Davis	3/1/2025
Site Administrator: Education/ Training Requirement	Dwight Mayfield	2/26/2025
Steering Committee	Dwight Mayfield	2/26/2025
Required Departmental Review/Approval	August Cervini	2/2/2025
Committee Chair(s)	Susan Kornetsky: Manager	2/1/2025
Contributor(s)	Susan Kornetsky: Manager	2/1/2025
Document Owner	Susan Kornetsky: Manager	2/1/2025

Applicability

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