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Boston Children's Hospital

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Effective 9/1/2022
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Owner Susan Kornetsky: Manager
Department Research
Applicability Boston Children's Hospital- Policies & Procedures

Legal Counsel Policy/Procedure

Internal Approval

SVP, Research

EVP & Chief Science Officer, Research

Scope

This policy describes the process by which the Institutional Review Board (IRB) receives legal counsel from the Office of the General Counsel (OGC) concerning local, state, and federal laws and regulations.

Policy Statements

The Office of General Counsel (OGC) will work closely with the Senior Director of Clinical Research Compliance and the Chair of the Institutional Review Board (IRB) to provide the IRB with accurate and timely advice regarding the nature, interpretation, and impact of pertinent local, state, and federal laws and regulations as they relate to any matter within the jurisdiction of the IRB.

1. To promote a close working relationship between the IRB and the OGC, the General Counsel, or the General Counsel's attorney-designee from within OGC, will be designated as a nonvoting member of the IRB.
2. At the request of the Senior Director of Clinical Research Compliance or the Chair of the IRB, the General Counsel, or their designee, will attend meetings to address issues within the IRB's jurisdiction, and will assist in educational efforts for the IRB and investigators.
3. The General Counsel, or their designee, will participate in the resolution of every issue that involves:
    a. legal noncompliance in the review of policies
    b. assisting the IRB in reaching and making determinations, on a protocol-specific or

subject-specific basis

c. whether minor subjects have the capacity to consent under applicable research regulations

d. implementing decisions that raise issues of legal compliance

Given the fact-specific nature of many these issues, they will be resolved on a fact-sensitive, case-by-case basis that is consistent with applicable regulations, laws, and policies.

Education and Resolution Assistance

The General Counsel, or their designee, will also educate and assist in the resolution of issues that arise under applicable federal and state laws and regulations, including, for example:

1. laws and regulations that affect privacy (such as federal HIPAA and state privacy standards), and
2. other laws and regulations that affect the conduct of research (such as those administered by the Food and Drug Administration, the National Institutes of Health, the Office of Human Research Protections, and the Office of Research Integrity).

Policy Drafting

The OGC will assist the Senior Director of Clinical Research Compliance in drafting policies and forms that comply with statutory and regulatory requirements, and in creating template language that reflects these requirements.

1. The IRB staff will verify the inclusion of such provisions when reviewing pertinent forms.
    a. For example, IRB staff will assess whether particular protocols might potentially uncover unreported child abuse or neglect; in such instances, the informed consent is to include specific language that informs parents and patients of a clinician's statutory obligation to report circumstances in which possible abuse or neglect could reasonably be inferred.

Procedures

Laws of the Commonwealth of Massachusetts

At regularly convened meetings of the IRB or otherwise, the General Counsel, or their designee, will address for the IRB, the Senior Director of Clinical Research Compliance, the Chair of the IRB, and/or investigators the applicability and interpretation of pertinent federal, state, and local laws and regulations, as well as evolving case law and regulatory guidance. This will include, without limitation, the applicability and interpretation of the following Laws of the Commonwealth of Massachusetts:

1. **Laws that protect consent:**
    a. A minor's right to consent, 112 MGL 12E
    b. Drug dependent minors, 112 MGL 12E1/2

c. Emergency treatment of minors,112 MGL 12F

2. **Laws that protect or affect confidentiality**, such as the General Law Patient Bill of Rights, 111 MGL 70E
3. **Laws that protect various forms of records:** (e.g.,
    a. Venereal disease, 111 MGL 119
    b. HIV testing and results, 111 MGL 70F
    c. Drug abuse treatment, 111E MGL 18
    d. Alcohol abuse treatment, 111B MGL 11
4. **Laws that privilege various clinical relationships**
    a. Social worker-patient privilege, 112 MGL 135
    b. Psychotherapist-patient privilege, 233 MGL 20B
    c. Psychologist-patient privilege, 112 MGL 129A
    d. Domestic violence counselors, 233 MGL 20K
5. **Laws that provide for mandatory reporting**
    a. Child abuse and neglect reporting, 119 MGL 51A
    b. Infectious disease reporting, 111 MGL 6
6. **Genetic testing,** 111 MGL 70G (Not applicable to IRB-approved studies)
7. **Fetal experimentation**, 112 MGL 12J
8. **Research projects that involve narcotics** and investigational drugs, 94C MGL 8 (Providing registration of investigators and for annual review.)
9. **Consent requirements for autopsy tissue**, 105 CMR 130.382 – 130.387. In June 7, 2004 the state Department of Public Health promulgated regulations regarding procedures required for autopsy consents including disposition of organs following autopsy.
    a. The regulations require the need:
        i. to obtain consent for an autopsy
        ii. to return any organs removed during the autopsy (except those needed for prolonged fixation or detailed exam to complete the autopsy) with the body unless the person authorizing the autopsy directs other otherwise, and
        iii. to provide the individual who consents to autopsy with a copy of the consent form.
    b. The regulations specifically address the need to:
        i. have a separate section of the consent address disposition of the organs following autopsy and
        ii. an opportunity to designate the disposition of the organs for research purposes.

At the time of the application, Boston Children's Hospital is in the process of revising the autopsy consent to include a specific choice for allowing tissues and organs removed during an autopsy to be used for research purposes.

10. **Other laws and regulations that affect pharmaceuticals and controlled substances**, Chapter 94C
11. **Inclusion of wards of state in research,** 110 CMR 16.00 (Department of Social Services)

Through the above efforts, through the General Counsel's role on other Boston Children's Hospital committees, including the Medical Staff Executive Committee (MSEC), and through the General Counsel's own reporting relationships, the OGC will support the IRB's efforts to maintain an integrated institutional compliance program at Boston Children's Hospital, and will reinforce the independence and authority of the IRB under applicable law and Boston Children's Hospital policy.

Related Content

- Commonwealth of Massachusetts General Laws
- IRB Policies
  - Special Considerations: Assent/Parental Permission ***(For more information on*** laws of the Commonwealth of Massachusetts and consent)
  - Pregnant Women, Fetuses, and Neonates (For more information on Massachusetts law, 112 MGL 12J on fetal experimentation)

Approval Signatures

Step Description	Approver	Date