Legal Counsel

Purpose

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

Policy

The Office of General Counsel (OGC) will work closely with the 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.

Procedures

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. At the request of the Director of Clinical Research Compliance or the Chair of the IRB, the General Counsel, or his or her designee, will attend meetings to address issues within the IRB's jurisdiction, and will assist in educational efforts for the IRB and investigators. The General Counsel, or his or her designee, will participate in the resolution of every issue that involves legal noncompliance, in the review of policies, and in assisting the IRB in reaching and making determinations, on a protocol-specific or subject-specific basis, whether minor subjects have the capacity to consent, under applicable research regulations and 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 laws, regulations, and policies.

At regularly convened meetings of the IRB or otherwise, the General Counsel, or his or her designee, will address for the IRB, the 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:

- **Laws that address a minor's right to consent** (e.g., 112 MGL 12E [drug dependent minors], 112 MGL 12F [emergency and other treatment of minors and emancipated minors]). (See IRB Policy: ***Special Considerations: Assent/Parental Permission*).**
- **Laws that protect or affect confidentiality**, such as the general Patient Bill of Rights (111 MGL 70E); laws that protect various forms of records (e.g., 111 MGL 119 [venereal disease], 111 MGL 70F [HIV testing and results], 111E MGL 18 [drug abuse treatment], 111B MGL 11 [alcohol abuse treatment]); and laws that privilege various clinical relationships (e.g., 112 MGL 135 [social worker-patient privilege], 233 MGL 20B

[psychotherapist-patient privilege], 112 MGL 129A [psychologist-patient privilege], 233 MGL 20K [domestic violence counselors]).

- **Laws that provide for mandatory reporting** (e.g., 119 MGL 51A [child abuse and neglect reporting],]111 MGL 6 ([infectious disease reporting]). (See text below)
- **Genetic testing** (***111 MGL 70G***) (Not applicable to IRB-approved studies.)
- **Fetal** experimentation (112 MGL 12J) (See IRB Policy: ***Pregnant Women, Fetuses, and Neonates***).
- **Research projects that involve narcotics** and investigational DRUGS (94C MGL 8) (Providing for registration of investigators and for annual review.)
- **Consent requirements for autopsy tissue** (105 CMR 130.382 – 130.387).
  In June7, 2004 the state Department of Public Health promulgated regulations regarding procedures required for autopsy consents including disposition of organs following autopsy. The regulations require:
- the need to obtain consent for an autopsy,
- the need 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
- the need to provide the individual who consents to autopsy with a copy of the consent form.
    - The regulations specifically address the need to have a separate section of the consent address disposition of the organs following autopsy and 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.
- **Other laws and regulations that affect pharmaceuticals and controlled substances** (94C)
- **Inclusion of Wards of State in Research: 110 CMR 16.00 Department of Social Services.**

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, laws and regulations that affect privacy (such as federal HIPAA and state privacy standards), and 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).

The OGC will assist the 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.

The IRB staff will verify the inclusion of such provisions when reviewing pertinent forms. 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.

Through the above efforts, through the General Counsel's role on other Boston Children's Hospital committees, including the Medical Staff Executive Committee, 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

IRB Policies

Pregnant Women, Fetuses, and Neonates

Special Considerations: Assent/Parental Permission

Document Attributes

Title	**Legal Counsel**		
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