

Institutional Review Board (IRB) Policies & Procedures Manual



Document: irbm-001-001-ethical-statement.docx

Statement of Ethical Principles and Regulatory Requirements for Human Subject Protection

Purpose

This policy defines the ethical principles, observed regulatory requirements, and procedures for human subject protection at Boston Children's Hospital.

Policy & Procedure

Ethical Principles

Boston Children's Hospital (BCH) adheres to the ethical principles and guidelines for the protection of human research subjects set forth in the Belmont Report. These principles and guidelines include respect for persons, beneficence, and justice.

Autonomy: Individuals are to be treated as autonomous agents, and persons with diminished autonomy are entitled to protection. The principle of respect for persons encompasses two moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

Beneficence: Individuals are to be treated in an ethical manner by respecting their decisions, protecting them from harm, and striving to secure their well-being. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. Two general rules are complementary expressions of beneficent actions:

1. do no harm, and
2. maximize possible benefits and minimize possible harms.

Justice: The benefits and burdens of research are to be shared fairly. An injustice occurs when some benefit to which a person is entitled is denied without good reason or is imposed unduly. There are several widely accepted formulations for the just distribution of burdens and benefits. Each formulation embraces a basis for the distribution of burdens and benefits. These formulations are to each person an equal share:

1. according to individual need.
2. according to individual effort.
3. according to societal contribution; and
4. according to merit.

Department of Health and Human Services Regulations (HHS 45 CFR 46)

Boston Children's Hospital holds a federal-wide assurance (FWA 00002071, IRB00000352) from the Office of Human Research Protection. Boston Children's Hospital operates in full compliance with all applicable federal, state, and local laws and regulations, and with the Federalwide Assurances (FWAs) and incorporated "Terms of the Federalwide Assurance. The

regulations under 45 CFR 46, including all of Subparts B, C, and D, provide the practical basis for the review and approval of all research at BCH regardless of funding, however Boston Children's Hospital may choose to not approve all 45 CFR 46 (including the subparts) in non-federally-funded research where the research warrants deviation and other appropriate human protection safeguards exist.

BCH requires all research that involves human subjects research that is conducted by BCH staff on its premises or under its sponsorship, whether or not supported by external funding, to be reviewed and approved by the IRB.

This policy also applies to BCH staff who conduct research at other hospitals, schools, institutions, community groups, or other places external to BCH. Individuals who are not affiliated with CH, but who participate in studies that use BCH patients, must also abide by these policies and procedures.

Food and Drug Administration Regulations

Boston Children's Hospital participates in clinical research that falls under the jurisdiction of the Food and Drug Administration. BCH complies with the regulations found under 21 CFR 50 (Informed Consent); 21 CFR 50, Subpart D (Safeguards for Children); 21 CFR 56 (IRB Regulations); 21 CFR 312 (Investigational New Drug Applications, IND); 21 CFR 361 (Radioactive Drugs); 21 CFR 612 (Biological Products); and 21 CFR 812 (Investigational Device Exemptions).

Other Federal Funding Agencies

If funded by other federal agencies that have specifications, their requirements will be applied. The most frequent are:

- Dept of Education 34 CFR Part 97
- Department of Defense 32 CFR 219
- NSF 45 CFR 690
- Dept of Energy 10 CFR part 745
- Dept of Justice 28 CFR 46

International Research

Any transnational research activities that are conducted under the auspices of the Boston Children's Hospital must be conducted consistent with the ethical principles set forth in the Boston Children's Hospital Research Protection Program and must meet equivalent levels of participant protection as research conducted at Boston Children's Hospital.

Both investigators and the IRB must take into consideration local laws and cultural context and make sure the research complies with the local regulations. When research is conducted internationally the Boston Children's Hospital IRB will require IRB/Ethics Committee review at the local site for consideration of the local research context and regulations. Documentation of this review will be required. Additionally, the IRB may request the use of local consultants or rely on one of its members with personal knowledge of local context.

The IRB, investigators and research staff are urged to refer to the OHRP website that provides links to key regulatory and ethical guidance for countries outside the United States. This site may be found at <http://www.hhs.gov/ohrp/international/index.html>

In addition, the IRB and investigator will take into consideration the **Council for International Organizations of Medical Sciences *International Ethical Guidelines for Biomedical Research Involving Human Subjects*** when reviewing international research

Commonwealth of Massachusetts

Boston Children's Hospital complies with Massachusetts state regulations. The two regulations specific to research are:

1. Investigational Drugs

This regulation requires investigators to obtain a license from the State of Massachusetts in order to administer an investigational drug or Schedule II drug during the conduct of a research protocol. For academic institutions, the state permits department chairs to hold a license for any investigators working in the department. The license is renewed annually, and the cost of the license is covered by the institution.

2. Massachusetts Fetal Research Statute, Section 12J of MGL, Chapter 112 (FHS)

The Fetal Research statute prohibits research on fetuses; however, two exceptions to this prohibition apply. These two exceptions are for protocols that meet the definition of 1) therapeutic exception; or 2) "no substantial jeopardy" exception. The definition of fetus extends to a neonate from birth to 28 days of life. For additional information, please see the IRB policy: ***Pregnant Women, Fetuses, and Neonates***.

Other Massachusetts Laws that Impact Clinical Research

Although the following laws do not pertain specifically to research, they may impact research and are to be taken into consideration as necessary.

- Laws that address a minor's right to consent (e.g., 112 MGL 12E, drug dependent minors; and 112 MGL 12F, emergency and other treatment of minors and emancipated minors)
- Laws that protect or affect confidentiality (e.g., 111 MGL 70E, the Patient Bill of Rights); 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; and 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; and 233 MGL 20K, domestic violence counselors),
- Consent requirements for autopsy tissue (105 CMR130.00000)
- Laws that provide for mandatory reporting (e.g., 119 MGL 51A, child abuse and neglect reporting; and 111 MGL 6, infectious disease reporting)
- genetic testing (111 MGL 70G)

Related Content

IRB Policy

Pregnant Women, Fetuses, and Neonates

Federal Reference

Council for International Organizations of Medical Sciences: International Ethical Guidelines for Biomedical Research Involving Human Subjects

The Belmont Report

OHRP: **International Research**

Document Attributes

Title	Statement of Ethical Principles and Regulatory Requirements for Human Subject Protection		
Author	Susan Kornetsky	Dates Reviewed/ Revised	4/1/2005 7/17/2007 07/19/2007 03/21/2008 4/28/2010 5/1/2015
Reviewed/ Revised by	Susan Kornetsky		
Copyright	©Boston Children’s Hospital, 2020	Last Modified	2/12/2020
Approved	<hr/> Susan Kornetsky Director of Clinical Research Compliance <hr/> August Cervini, MBA Vice President for Research Administration		