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

Statement of Ethical Principles and Regulatory Requirements for Human Subject Protection Policy/ Procedure

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

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.

Policy Statements

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

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**.

Procedures

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

A. Boston Children's Hospital holds a federal-wide assurance (FWA 00002071, IRB00000352) from the Office of Human Research Protection (OHRP).

B. 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.

C. 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 Boston Children's Hospital 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.

D. Boston Children's Hospital requires all research that involves human subjects research that is conducted by hospital staff on its premises or under its sponsorship, whether or not supported by external funding, to be reviewed and approved by the IRB.

    1. This policy also applies to hospital staff who conduct research at other hospitals, schools, institutions, community groups, or other places external to the hospital.
    2. Individuals who are not affiliated with Boston Children's Hospital, but who participate in studies that use hospital 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.

Boston Children's Hospital complies with the regulations found under:

A. Informed Consent, 21 CFR 50
B. Safeguards for Children, 21 CFR 50, Subpart D
C. IRB Regulations, 21 CFR 56
D. Investigational New Drug Applications (IND), 21 CFR 312
E. Radioactive Drugs, 21 CFR 361
F. Biological Products, 21 CFR 612
G. Investigational Device Exemptions, 21 CFR 812

Other Federal Funding Agencies

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

A. Dept of Education, 34 CFR Part 97
B. Department of Defense, 32 CFR 219
C. National Science Foundation (NSF), 45 CFR 690
D. Department of Energy, 10 CFR part 745
E. Department of Justice, 28 CFR 46

International Research

A. 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.
B. Both investigators and the IRB must take into consideration local laws and cultural context and make sure the research complies with the local regulations.
C. 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.
    1. Documentation of this review will be required.
    2. Additionally, the IRB may request the use of local consultants or rely on one of its members with personal knowledge of local context.

D. The IRB, investigators and research staff are urged to refer to the Office of Human Research Protections (OHRP) website that provides links to key regulatory and ethical guidance for countries outside the United States.

E. 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:

A. 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.

B. Massachusetts Fetal Research Statue, Section 12J or MGL, Chapter 112 (FHS). The Fetal Research statue 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.

C. 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:

1. Minor's right to consent, 112 MGL 12E
2. Drug dependent minors, 112 MGL 12E1/2
3. Emergency and other treatment of minors and emancipated minors, 112 MGL 12F
4. Protection or affect confidentiality (Patient's rights law), 111 MGL 70E
5. Protection of various forms of records, 111 MGH 119
6. Venereal disease, 112 MGL 12
7. HIV testing and results, 111 MGL 70F
8. Drug abuse treatment, 111E MGL 18
9. Alcohol abuse treatment, 111B MGL 11
10. Various clinical relationships: Social worker-patient privilege,112 MGL 135; psychotherapist-patient privilege; 233 MGL 20B, psychologist-patient privilege, 112 MGL 129A; and domestic violence counselors, 2333 MGL 20K
11. Consent for autopsy tissue, 105 CMR130.00000
12. Mandatory reporting of child abuse and neglect, 119 MGL 51A
13. Infectious disease reporting, 111 MGL 6
14. Genetic testing, 111 MGL 70G

15. Narcotics and investigational drugs, 94C MGL
16. Other laws and regulations that affect pharmaceuticals and controlled substances, Chapter 94 C
17. Inclusion of wards of state in research, 110 CMR 16.00 (Department of Social Services)
18. Incarcerated youth under services of DYS- MGL Chapter 30A, Section 1B and Chapter 18A, Section 2.

References/Citations

Belmont Report

Office of Human Research Protections: ***International Research***

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

Related Content

- Department of Health and Human Services Regulations (HHS 45 CFR 46)
- U.S. Food & Drug Administration CFR – Code of Federal Regulations Title 21
- Commonwealth of Massachusetts General Laws
- IRB Policy: Pregnant Women, Fetuses, and Neonates (For additional information on Massachusetts Fetal Research Statute)

Approval Signatures

Step Description	Approver	Date
Co-chair Approval	David Davis	3/1/2025
Site Administrator: Education/ Training Requirement	Dwight Mayfield	2/25/2025
Steering Committee	Dwight Mayfield	2/25/2025
Required Departmental Review/Approval	August Cervini	1/17/2025
Committee Chair(s)	Susan Kornetsky: Manager	1/17/2025
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Applicability

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