

<b>THE NORTH SHORE MEDICAL CENTER Institutional Review Board (IRB) POLICIES AND PROCEDURES</b>	<b>IRB Policy Number:</b> 001.1
<b>Title:</b> <i>IRB Purpose, Principles and Responsibilities</i>	<b>Page:</b> 1 of 5
<b>Written by:</b> _____ Laura W. Knight, MPH; Sr. IRB Administrator	<b>Date this issue:</b> April 2008 <b>Previous issue(s):</b> 4/18/01, 2/24/04, 11/15/04
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## I. MISSION AND PURPOSE

The mission and purpose of the North Shore Medical Center (NSMC) Institutional Review Board (IRB) is to determine and certify that all human subjects research projects (regardless of funding) conducted by NSMC faculty, staff, and students or otherwise conducted under NSMC IRB oversight, conform to the regulations and policies regarding the rights, dignity, welfare, safety, and privacy of human subjects set forth by the Department of Health and Human Services (DHHS) in 45 CFR 46 and the Federal Drug Administration (FDA) in 21 CFR 50 and 56. The NSMC IRB shall be committed to following the letter and spirit of all applicable federal, state, and local laws, regulations and guidance. The responsibility for the protection of the rights and welfare of human subjects shall be shared both by the institution and the investigators conducting the research.

## II. DEFINITIONS

Department of Health and Human Services (DHHS) definitions:

**Research:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(d)]

**Human Subject:** A living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

**Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

**Interaction** includes communication or interpersonal contact between investigator and subject.

**Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. [45 CFR 46.102(f)(1)(2)]

Food and Drug Administration (FDA) definitions:

**Clinical Investigation:** Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the

Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical studies. The terms *research*, *clinical research*, *clinical study*, *study*, and *clinical investigation* are deemed to be synonymous [21 CFR 50.3(c) and 21 CFR 56.102(c)]

**Human Subject:** An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. [21 CFR 50.3(g) and 21 CFR 56.102(g)]

### III. GOVERNING PRINCIPLES

The NSMC IRB is guided by the *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, generally known as the "Belmont Report". This fundamental commitment to the protection of human participants applies to all NSMC research involving human participants, regardless of the funding source. The principles found in the Belmont Report are summarized as follows:

**Respect for Persons** – Individuals should be treated as autonomous agents. They should voluntarily enter into research by being adequately informed. Special protection should be given to individuals with diminished autonomy and/or of special circumstances since they may not be able to make a considered judgment even if they are adequately informed. One group entitled to special protections is prisoners who may be subtly coerced or unduly influenced.

**Beneficence** – Researchers are obligated to do no harm by maximizing possible benefits and reducing possible risks to subjects. In some cases where research may pose risk to individual subjects with no direct benefit to them the principle of beneficence requires careful assessment of the benefits to others or to society.

**Justice** – The risks of research should be equally distributed and should not unduly involve persons from groups unlikely to be among the beneficiaries of the research. Selection of individuals or classes of individuals should be fair. Vulnerable classes of subjects should be given special protection and not be unduly selected as research subjects due to their ready availability or dependent status.

### IV. APPLICABLE LAWS

#### Federal Regulations:

DHHS Regulations 45 CFR Parts 46 and 164

FDA Regulations 21 CFR Parts 11, 50, 54, 56, 312, 812

#### State Statutes and Codes:

M.G.L. c. 94C §8 (Controlled Substances in Research)

M.G.L. ch. 111L (Human Embryonic Stem Cell Research)

M.G.L. ch. 111, §70E (Patients Rights/Informed Consent)

M.G.L. c.111 § 70F (Consent to HIV/AIDS Testing)

M.G.L. c.111 § 70G (Genetic Privacy)

M.G.L. c.112, §12F (Consent by Minors)

M.G.L. c.112, §12J (Experimentation on Fetuses)

M.G.L. c.201, §§6-6B (Guardianships)

M.G.L. c.201D,6; 2-1-2 to 201-4 (Health Care Proxies)

104 C.M.R. 31.00 (Department of Mental Health Research)

105 C.M.R. 700.009 (Controlled Substances in Research)

105 C.M.R. 960.000 (Human Embryonic Stem Cell Research)

115 C.M.R. 10.00 (Department of Mental Retardation Research)

## V. FEDERALWIDE ASSURANCE (FWA)

The NSMC IRB (single IRB) holds a Federalwide Assurance of Protection for Human Subjects (Department of Health and Human Services), FWA00007262, in which it agrees to uphold the ethical principles of the Belmont Report and to apply the Code of Federal Regulations (45 CFR Part 46) to all research involving human subjects regardless of sponsorship or support. The FWA has been approved by the Office of Human Research Protections (OHRP) and is updated as necessary when information changes.

## VI. ORGANIZATION AND RESPONSIBILITIES

### 1. Institutional Official

The NSMC IRB is overseen by the Chief Medical Officer (CMO)/Senior Vice President (SVP) for Medical Affairs. The CMO/SVP Medical Affairs also serves as the "Institutional Official" (IO), the term assigned to a senior official of the institution who executes the FWA (refer to Section V).

The IO understands the institution's responsibilities under the FWA, assures the protection of human subjects of research, and assures that the IRB is knowledgeable about the local research context and will comply with the terms of the FWA. The IO ensures that the IRB is the sole entity that can grant approval for a human research protocol or designate review to another authorized IRB. The IO is responsible for:

- Setting the "tone" for an institutional culture of respect for human subjects;
- Ensuring effective institution-wide communication and guidance on human subjects issues;
- Ensuring that investigators fulfill their responsibilities;
- Facilitating participation in human subject education activities;
- Serving as a knowledgeable point of contact for OHRP, FDA, the Office of Research Integrity (ORI) and other relevant federal and state agencies;
- Serving as contact for concerns or suggestions regarding the NSMC IRB and the research review process; and
- Submitting required reports to OHRP, FDA, ORI and other relevant federal and state agencies.

Administratively, the IO is responsible for:

- Providing the IRB with adequate resources, such as staff support, space, equipment and other resources; and
- Supporting the authority, independence and decisions of the IRB.

### 2. Institutional Review Board

The NSMC IRB shall be responsible for the review of all human-subjects research and approval of all non-exempt human-subjects research and clinical investigations, or designation of review and approval to another authorized IRB, that are conducted by NSMC employees or agents (e.g., professional staff) in connection with their institutional responsibilities regardless of the source of funding.

The NSMC IRB shall follow written policies and procedures for the following specific responsibilities:

- Determining whether a research activity submitted for IRB review is human-subjects research or a clinical investigation subject to federal regulations;
- Determining exemptions from 45 CFR 46 and 21 CFR 56;
- Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and to the institution;
- Determining which projects require review more often than annually;
- Determining which projects need verification from sources other than the investigators that no material changes have occurred since the last review;

- Ensuring prompt reporting of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject;
- Ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of any unanticipated problems involving risks to subjects or others;
- Ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of any serious or continuing noncompliance with federal regulations or the requirements or determinations of the IRB;
- Ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of any suspension or termination of IRB approval; and
- Except when an expedited review procedure is used, reviewing proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

In addition, the IRB is responsible for the interpretation of governmental and institutional policies on human subjects.

### 3. Department Chairs/Chiefs

Department chairs/chiefs are responsible for the following:

- Ensuring that investigators conducting human-subjects research are qualified by training and experience to conduct the proposed research.
- Ensuring that investigators have sufficient resources (time, research personnel, and access to appropriate populations) and facilities to conduct the proposed research.
- For each protocol submitted to the IRB for approval, the department chair/chief must certify that s/he accepts responsibility for assuring adherence to federal and state research regulations and institutional policies governing the protection of human subjects, including applicable institutional credentialing requirements.

### 4. Investigators

Principal investigators (PIs) are responsible for the following:

- Protecting the rights and welfare of human subjects participating in research
- Commencing human-subjects research only with prior IRB and, as appropriate, other institutional approval of their protocols. The PI must have a staff appointment and may not be a resident or research fellow or trainee.
- For each protocol submitted to the IRB for approval, certifying that s/he accepts responsibility for assuring adherence to applicable federal and state research regulations and hospital policies relative to the protection of the rights and welfare of subjects enrolled in the research.
- Be qualified by training and experience to conduct the research and must be in compliance with NSMC Conflicts of Interest policy, including the Partners Human Research Committee *Financial Conflicts of Interest* policy.
- When the research involves the administration of a drug or use of a device for research purposes, the PI must be a licensed physician. Exceptions to this requirement are made by the NSMC IRB on a case-by-case basis: exceptions require a licensed physician co-investigator and approval of the department chair/chief.
- Ensuring compliance with the requirements of Massachusetts General Laws (M.G.L.) 94C Controlled Substances Act Section 8 governing research projects and studies. Investigators must fulfill annual registration and reporting requirements with the Commonwealth of Massachusetts Department of Public Health. The Commonwealth of Massachusetts works through the IRB to register all investigators and obtain annual reports on clinical investigations involving IND drugs, controlled substances or schedule II drugs that are being conducted at NSMC.

- PIs may delegate responsibilities to appropriately qualified co-investigators and research staff. However, co-investigators and research staff must be qualified by training and experience to perform these responsibilities. Additionally, co-investigators and research staff must be in compliance with the NSMC Conflicts of Interest Policy, as applicable. The PI remains responsible for the conduct of all persons to whom s/he delegates tasks.

**VII. RELATED POLICIES, REGULATIONS, AND REFERENCES:**

IRB Policy #002            IRB Jurisdiction and Authority