

<b>THE NORTH SHORE MEDICAL CENTER Institutional Review Board (IRB) POLICIES AND PROCEDURES</b>	<b>IRB Policy Number:</b> 004.1
<b>Title:</b> <i>IRB Composition and Roster</i>	<b>Page:</b> 1 of 5
<b>Written by:</b> _____ Laura W. Knight, MPH; Sr. IRB Administrator	<b>Date this issue:</b> June 2008 <b>Previous issue(s):</b> 4/18/01, 2/24/04, 11/15/04
<b>Approved by:</b> _____ Charles Bockoff, MD; Chairman, NSMC IRB	<b>For further information contact:</b> IRB office 781-477-3678

## I. PURPOSE

This policy defines the composition and requirements of the North Shore Medical Center (NSMC) Institutional Review Board (IRB) membership.

## 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)]

Other definitions:

**Immediate Family Member:** defined as spouse, domestic partner, child, parent, or sibling.

**Affiliated:** defined as having an employment relationship with, a professional relationship with, a paid consultant relationship with, or a trustee/governing board member relationship with, or being a student of, the entity or component.

### III. PROCEDURE

#### 1. Membership

1.1 The NSMC IRB shall be composed of at least five (5) members with varying backgrounds to promote complete and adequate review of human-subjects research and clinical investigations commonly conducted at NSMC.

1.2 Members shall include both men and women, members of minority groups and shall include:

- physicians;
- scientists;
- at least one member who is unaffiliated with the institutions and who is not part of the immediate family of a person who is affiliated with the institution; and
- at least one member whose primary concerns are in nonscientific areas. Examples include but are not limited to lawyers, ethicists, and clergy.

1.3 No qualified individual shall be rejected from the membership on the basis of race, gender, creed, religion, color, national origin, age, disability, or sexual orientation.

#### 2. Recruitment and Selection of Members

2.1 Affiliated physician, scientist, and nonscientist members shall be recruited by the IRB Chairperson, by the Chief Medical Officer/Senior Vice President of Medical Affairs through the chairs/chiefs of the hospital departments or units, and/or by current IRB members.

2.2 Non-affiliated physician, scientist, and nonscientist members shall be recruited through current IRB members or through the volunteer department or various community agencies or groups.

2.3 New members shall be recruited as needed to ensure that the IRB membership continues to include individuals with varying backgrounds and the necessary experience.

2.4 Upon request, current IRB members may review the qualifications of potential members prior to their appointment to the IRB and communicate any issues to the IRB Administrator and IRB Chairperson.

#### 3. Periodic Review of the Membership

3.1 The IRB membership shall be reviewed at least annually to determine if the membership continues to include individuals with varying backgrounds and the experience and scientific or scholarly expertise needed to review the scope of biomedical and behavioral research conducted at NSMC. The IRB Chairperson and Administrator shall conduct this review.

3.2 The IRB Administrator shall be responsible for compiling information about research protocols reviewed at convened meetings to assess the scope of biomedical and behavioral research reviewed by the NSMC IRB.

#### 4. Procedures for Appointment and Reappointment

4.1 Prospective members shall be asked to: (1) attend a convened meeting of the NSMC IRB as a guest; (2) complete a conflict of interest statement; (3) provide a copy of their curriculum vitae

or resume, (4) complete the Collaborative Institutional Training Initiative (CITI) program for biomedical research; and (5) complete the NSMC IRB member orientation.

4.2 The IRB Chairperson shall be responsible for notifying the individual in writing of his/her appointment and, when applicable, the relevant Department Chair/Chief. When the individual's membership is rejected, the IRB Chairperson shall be responsible for providing the individual with the basis for rejection.

5. Term of Appointment

5.1 There shall be no term limits; however, members may be removed by the IRB Chairperson for cause as described elsewhere in this document.

6. Resignation

6.1 Any member may at any time resign from the IRB by a written resignation submitted to the IRB Chairperson. Upon resignation, the member will be removed from the IRB roster.

7. Suspension or Removal of Members

7.1 The IRB Chairperson may suspend or remove for cause any member of the IRB; provided, however, that such member shall have been given reasonable notice of the grounds for the suspension or removal and an opportunity to be heard. For this purpose, cause (with respect to a voting member) shall include the failure to attend more than two-thirds (2/3) of the convened meetings in a calendar year of the IRB without excuse or the failure to perform reviews when assigned as a primary reviewer without prior notice or excuse.

8. Membership Records and Roster

8.1 The IRB office shall maintain a roster of IRB members to include the following information:

- Name;
- Earned degrees;
- Scientific status (i.e., physician-scientist, other scientist, or non-scientist);
- Experience and expertise, such as board certifications, licenses;
- Representative capacity (e.g., children, pregnant women, prisoners, economically disadvantaged, educationally disadvantaged, or cognitively impaired adults); and
- Affiliation, if any, with NSMC entity.

8.2 Members shall be designated as either: (1) physician-scientists, other scientists, or nonscientists; and (2) affiliated or unaffiliated member.

8.2.1 Physician-Scientists - Members who have a medical degree shall be categorized as physician-scientists.

8.2.2 Other Scientists - Members who have substantive training or experience in a scientific discipline (i.e., behavioral or biomedical) or in a scientific method shall be categorized as other scientists. This includes individuals with doctoral or graduate degrees in medical or scientific areas.

8.2.3 Nonscientists - Members who do not have substantive training or experience in a scientific discipline (i.e., behavioral or biomedical) or in a scientific method shall be categorized as nonscientists.

8.2.4 Affiliated - Members, or their immediate family members, who are affiliated with any North Shore Medical Center (NSMC) entity shall be considered affiliated.

8.2.5 Unaffiliated Members, or their immediate family members, who are not affiliated with any NSMC entity shall be considered unaffiliated.

8.3 The IRB office shall be responsible for updating the membership roster as needed when membership changes and submitting the updated information to OHRP as required by the institutions' FWA. IRB rosters shall be retained for at least six (6) years and shall be made

available upon request, when applicable, to the NIH and FDA for inspection and copying onsite during normal business hours. Individual membership records shall be retained by the IRB office for at least six (6) years from date of last service.

- 8.4 Member appointment letters, CVs and conflict of interest forms shall also be retained on file in the IRB office.

9. Orientation, Education, and Training

- 9.1 *Orientation* - The IRB Administrator shall provide new members with all NSMC IRB policies, relevant federal and state regulations and checklists and forms commonly used by the NSMC IRB and review any questions or concerns.

- 9.2 *Education and Training* - Members shall be required to complete the Collaborative Institutional Training Initiative (CITI) program for biomedical research prior to becoming a voting member and complete a CITI refresher course every 2 years thereafter in accordance with IRB Policy #021.

- 9.3 *Continuing Education and Training* - All members shall receive copies of new and updated guidance documents from the FDA, OHRP, or other governing agencies. A portion of each convened meeting shall be dedicated to review and/or discussion of educational topics (e.g., review of case studies, new or revised IRB policies, etc). When possible, educational seminars will be conducted at least on an annual basis.

10. Attendance

- 10.1 Voting members shall be expected to attend at least two-thirds (2/3) of the scheduled IRB meetings in each calendar year. Attendance records shall be reviewed annually.

- 10.2 Prior to each convened meeting, members are asked if they will attend the meeting in order to determine whether the requirement for quorum is met and that members with the appropriate expertise will be in attendance.

- 10.3 The IRB Administrator is responsible for ensuring that at least one member attending the meeting has the necessary knowledge and expertise to review each of the protocols listed on the agenda (including when the agenda contains protocols involving vulnerable populations). If none of the attending members have the necessary expertise, either a consultant will be utilized (refer to section 12) and/or the review of the protocol will be deferred until the necessary expertise is available.

11. IRB Chairperson and IRB Administrator

- 11.1 Qualifications The IRB Chairperson shall be a physician, a member of the NSMC Medical Staff, and appointed by the Chief Medical Officer/Senior Vice President of Medical Affairs who serves as NSMC's Institutional Official. Chairpersons shall be selected from either among IRB members with three (3) or more years of experience. Alternatively, the IRB Chairperson may be selected from outside the IRB as long as he/she has the appropriate expertise. There shall be no term limits placed on length of service. The IRB Chairperson (and any designated alternate or vice-chair) shall be provided with orientation and training commensurate with their level of expertise.

The IRB Administrator shall be selected by the IRB Chairman and/or the Institutional Official. The IRB Administrator shall have extensive knowledge of federal, state, and local laws and regulations governing human-subjects research acquired through at least three (3) years of direct IRB experience or experience in clinical research.

The IRB Chairperson and Administrator shall be required to attend at least one human-subjects protection-related local, regional or national conference every two years.

## 11.2 Periodic Review

The IRB Chairperson shall be reviewed at least annually by the Institutional Official. The IRB Administrator shall be reviewed annually by the Institutional Official, with input from the IRB Chairperson, in accordance with NSMC Human Resources Policies and Procedures.

## 12. Use of Consultants

12.1 When, in the opinion of the IRB Chairperson or IRB Administrator, the IRB membership lacks the expertise needed to review the protocol, the IRB Chairperson or IRB Administrator identifies potential expert consultants to supplement or provide expertise not available on the NSMC IRB.

12.2 Additionally, the IRB may vote to defer action on a protocol and may require an expert in the scientific area or discipline to review the research and provide consultation to the IRB. Potential consultants will be identified and agreed upon by the IRB, or as indicated above.

12.3 Consultants are subject to the Conflicts of Interest Policy noted in Section 13 and must confirm in writing that they have no conflict of interest. If the consultant agrees to review the research and the consultant has no conflict of interest, s/he is provided with all of the forms and documents submitted to the IRB for review.

12.4 Consultants are asked to attend the meeting to present their findings relative to the scientific merits of the study, the risks and potential benefits to subjects, and alternative treatments or procedures, and to answer questions; however, if the consultant is unavailable to attend the meeting, s/he may provide written comments for distribution or communication to the IRB members. Consultants are not voting members, and their attendance is recorded in the Minutes as guests (consultant).

## 13. Conflicts of Interest

13.1 IRB members are subject to the NSMC *Research Conflicts of Interest Policy*.

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

IRB Policy #002	IRB Jurisdiction and Authority
IRB Policy #021	Human Subjects Protections Training Requirement
IRB Policy #007	Research Conflicts of Interest