

THE NORTH SHORE MEDICAL CENTER Institutional Review Board (IRB) POLICIES AND PROCEDURES	IRB Policy Number: 011.1
Title: <i>Off-Site and Cooperative Research</i>	Page: 1 of 4
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I. PURPOSE

The purpose of this policy is to define the requirements and procedures the North Shore Medical Center Institutional Review Board (NSMC IRB) follows for review of non-exempt human-subjects research and clinical investigations conducted by employees or agents (e.g., professional staff) of NSMC at sites other than those owned or controlled by NSMC (off-site research) and for designation of review of research conducted at multiple locations (cooperative research).

II. SCOPE

The NSMC IRB must consider the local research context when reviewing non-exempt human-subjects research and clinical investigations being conducted by NSMC investigators off-site and must confirm that off-site research will be conducted in compliance with federal, state, and local laws and regulations, as well as the performance site's known institutional requirements.

Off-site non-exempt human-subjects research and clinical investigations reviewed by the NSMC IRB and cooperative research studies are subject to this policy.

III. 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)]

Off-Site Research: Research conducted by NSMC employees or agents (e.g., professional staff) at sites not owned or controlled by NSMC. Sites or spaces that are leased by NSMC are generally considered controlled by the hospital(s) for the purposes of this policy and thus fall under general NSMC IRB policies.

Cooperative Research: Research projects which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with federal regulations. To avoid duplication of efforts, an institution participating in a cooperative research project may enter into a joint review arrangement or elect to rely upon the review of another institution's qualified IRB for review as outlined below.

IV. PROCEDURE

1. Engagement of Performance Sites in Human-Subjects Research

The investigator must specify in the research application the sites at which employees or agents of NSMC will conduct the research, including any off-site locations.

1.1 Performance Sites Not Engaged in Human-Subjects Research

When the research will be conducted off-site at a performance site that is not engaged in human-subjects research, the NSMC IRB will require the site to provide original written documentation of approval of that institution or entity (e.g., schools, nursing homes, assisted living facilities, community centers) to use its facilities for research or, when applicable, approval of an involved governmental agency or authorities (e.g., ministry of health). The NSMC has a template agreement that may be used for this purpose.

1.2 Performance Sites Engaged in Human-Subjects Research

When the research will be conducted off-site at a performance site that is engaged in human-subjects research, the NSMC IRB will require original documentation of the performance site's Federalwide Assurance (FWA) and IRB approval. When the research is not federally-funded, in its discretion, the NSMC IRB may find it acceptable that the research has been reviewed and approved by other internationally recognized Institutional Ethics Committees.

2. Designation of IRB Review and Reliance Agreements

2.1 Reliance of Performance Sites on NSMC IRB

Institutions may seek permission to rely on the NSMC IRB for review of the research on the institution's behalf, under an IRB Authorization Agreement (IAA). If the NSMC IRB agrees to provide such review, the institution will be required to have its own FWA and will require that the IAA be executed before the research is initiated at the institution. All institutions with an FWA relying on NSMC for IRB review must add the NSMC IRB to their FWA. When the research is not federally-funded, in its discretion, the

NSMC IRB may find it acceptable that the research has been reviewed and approved by other internationally recognized Institutional Ethics Committees.

- 2.1.1 Where an NSMC Investigator collaborates with an external investigator who does not have an academic or institution affiliation (e.g., independent investigator), the NSMC IRB may agree to be the IRB of record for the external investigator following execution of an Investigator Authorization Agreement that outlines scope and responsibilities of the Investigator and NSMC.
- 2.1.2 Where an organization receives a federal grant and plans to collaborate with an NSMC Investigator on a research project, the organization must have a FWA and an IRB of record to receive federal funds. If the NSMC IRB agrees to be the IRB of record, an IAA must be executed before initiation of IRB review.

2.2 Reliance of NSMC IRB on Another Institution's IRB

The NSMC IRB may designate IRB review to another institution's IRB for cooperative research projects, under an IRB Authorization Agreement (IAA). In such cases, the other Institution must have a FWA. The NSMC IRB will require the IAA be executed before the research is reviewed by the other institution's IRB. The NSMC IRB must ensure that the other institution's IRB is added to the NSMC FWA.

2.2.1 Review of Local Research Context

The NSMC IRB Chairperson is responsible for reviewing all individual requests for designation of IRB review to another institution's IRB (under an existing IAA). The NSMC IRB Chairperson will consider the following local issues prior to designation:

- The types of subject populations likely to be involved;
- Method for equitable selection of subjects;
- Method for protection of privacy of subjects;
- Method for maintenance of confidentiality of data;
- Language(s) understood by prospective subjects;
- Method for minimizing the possibility of coercion or undue influence in seeking consent;
- Safeguards to protect the rights and welfare of vulnerable subjects.

For all research projects designated to another institution's IRB, the NSMC IRB staff is required to receive relevant communications regarding the conduct of the study. The NSMC IRB reserves the right to revoke designation of review to another institution's IRB at any time and become the IRB of record.

The NSMC IRB Chairperson may determine that there are issues that need to be reviewed locally and in those situations the NSMC IRB will remain the IRB of record and will be responsible for review of the research project.

3. Other Considerations

3.1 Domestic Performance Sites Outside Massachusetts

If a performance site is in a state other than Massachusetts, and there is a question about applicable state law, the NSMC IRB may consult with NSMC Legal Counsel and/or the Partners Office of the General Counsel (OGC) and may discuss with the site as necessary to confirm that requirements of applicable local laws will be met. If the site is relying on the NSMC IRB for review under an IAA, the

agreement may require the site to inform the NSMC IRB of specific applicable local legal requirements and policies affecting the research.

3.2 International Performance Sites

The NSMC IRB may rely on the performance site's IRB's assessment of the local research context. In such cases, the NSMC will require documentation of local IRB approval prior to NSMC review.

Additionally, the NSMC may gather information on the local research context either through the Principal Investigator, the use of consultants within the United States, or through teleconferencing with consultants at the international site. The NSMC may also call upon one of its members with personal knowledge of the local research context, such knowledge having been obtained through extended, direct experience with the research institution, its subject populations, and its surrounding communities.

4. Documentation

- 4.1 The Institutional Official is responsible for executing IAAs on behalf of NSMC. The NSMC IRB staff is responsible for retaining records of all executed IAAs for at least six (6) years from the date of completion of the research.
- 4.2 The NSMC IRB staff is responsible for retaining all documentation relating to IRB reliance determinations for at least six (6) years from the date of completion of the research.

V. RELATED POLICIES, REGULATIONS, AND REFERENCES

DHHS Regulations 45 CFR Part 46

FDA Regulations 21 CFR Parts 56