

THE NORTH SHORE MEDICAL CENTER Institutional Review Board (IRB) POLICIES AND PROCEDURES	IRB Policy Number: 002.1
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I. PURPOSE

This policy defines the jurisdiction and authority of the North Shore Medical Center Institutional Review Board (NSMC IRB).

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. JURISDICTION

The NSMC IRB is responsible for all human-subjects research and clinical investigations conducted by NSMC investigators or under the auspices of the institution, or in which the institution is otherwise engaged, regardless of the source of funding. This includes:

- Research sponsored by NSMC;
- Research involving NSMC patients or their private information
- Research involving the use of NSMC's private information to identify or contact subjects.
- Research conducted by or under the direction of employees or agents of NSMC in connection with their institutional responsibilities;
- Research conducted by or under the direction of any employee or agent of NSMC using any property or services of NSMC; or
- Research conducted by or under the direction of an individual employed by any NSMC-affiliated site and who is performing research at that site.

NSMC is engaged in human-subjects research whenever employees or agents (e.g., professional staff) of the institution intervene or interact with living individuals for research purposes or obtain individually identifiable private information for research purposes. NSMC is automatically considered to be engaged in human-subjects research whenever the institution receives a direct DHHS award to support such research. The NSMC IRB may decide to designate IRB review for studies under its jurisdiction to another authorized IRB in accordance with IRB Policy 011.

The NSMC institution includes, but is not limited to, various inpatient campus locations (Salem Hospital, Union Hospital, North Shore Children's Hospital) as well as outpatient campus locations (NSMC Heart Center, NSMC Cancer Center, NSMC Pediatric Inpatient Psychiatry at the Hunt Center, NSMC Women's Center).

IV. AUTHORITY

The NSMC IRB has the authority to review, approve, disapprove, require changes in, suspend or terminate approval of research or related activities involving human subjects. The NSMC IRB has the specific authority to:

- Determine whether a research activity submitted for IRB review is human-subjects research or a clinical investigation subject to federal regulations;
- Determine exemptions from 45 CFR 46 and 21 CFR 56;
- Approve, require modifications in (to secure approval of), or disapprove research activities involving human subjects, or designate review to another authorized IRB;
- Require progress reports from investigators;
- Oversee the conduct of research;
- Require a third party to observe the consent process;
- Suspend or terminate approval of a research activity;
- Place restrictions on a research activity;
- Request a directed audit or otherwise investigate, address, remedy, and report on incidences of noncompliance with legal, regulatory, or NSMC IRB requirements or determinations;
- Conduct reviews and inquiries regarding human-subjects research as needed to obtain information necessary for the fulfillment of the institutional responsibilities outlined in the institutions' Office for Human Research Protections (OHRP)-approved Federal Wide Assurance (FWAs); and
- Act as the HIPAA Privacy Board for research activities.

In exercising its authority, the NSMC IRB shall communicate its decisions regarding human-subjects research and clinical investigations to investigators and to the institution (as applicable).

The NSMC IRB does not have the authority to grant retroactive approval should a research study be initiated without prior NSMC IRB review.

1. Independence

The NSMC IRB shall exercise independence as the entity authorized to oversee human-subjects research at NSMC and is the final authority for all decisions regarding the protection and welfare of human subjects in research. Consistent with federal regulations, no one within the institution may overrule the decision of the NSMC IRB to disapprove research and allow the disapproved research to go forward. [45 CFR 46.112][21 CFR 56.112] However, research approved by the NSMC IRB may be subject to further institutional review and approval.

2. Undue Influence

In the event of undue influence (e.g., someone outside of the NSMC IRB seeks to influence the outcome of NSMC IRB review of a research activity), the IRB Administrator and Chair shall work with the Institutional Official (IO), as necessary, to remedy any concern. Responses to such a concern shall preserve the NSMC IRB's independence. Measures may include, for example, discussion between the IO and the person causing the undue influence and, when appropriate, discussion with such person's department chair or supervisor; limiting or removal of such person's privilege to conduct research; or recusal of the NSMC IRB member upon whom undue influence was exerted.

V. RELATED POLICIES, REGULATIONS, AND REFERENCES:

- IRB 001 IRB Jurisdiction and Authority
- IRB 008 IRB General Review Procedures
- IRB 011 Designation of IRB Review

DHHS Regulations 45 CFR Part 46
FDA Regulations 21 CFR Parts 50, 56