

THE NORTH SHORE MEDICAL CENTER Institutional Review Board (IRB) POLICIES AND PROCEDURES	IRB Policy Number: 017.1
Title: <i>IRB Quality Assurance Program</i>	Page: 1 of 4
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I. PURPOSE

The purpose of this policy is to define the quality assurance program of the North Shore Medical Center Institutional Review Board (NSMC IRB). The goal is to increase the quality and performance of the NSMC IRB as well as to ensure compliance with federal regulations. The NSMC IRB is subject to periodic assessment for purposes of assuring the protection of human research subjects through compliance and quality improvement activities.

II. SCOPE

This policy covers all aspects of the NSMC IRB as well as principal investigators and their staff. All research involving human subjects conducted at NSMC, whether funded or unfunded, is within its purview.

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)]

Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. 45 CFR 46.102(i), 21 CFR 50.3(k)

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)]

IV. PROCEDURE

The IRB has developed a quality assurance program to improve human research protections at NSMC. The primary tool is the audit of investigator research records and IRB activities and may be performed for-cause, as a result of a complaint from research subjects or others, or per a periodic audit schedule. In addition, studies that involve a potential high-risk to subjects, vulnerable populations, and/or large numbers of subjects may be selected for audit.

1. Investigator Research Audits

- 1.1 The NSMC IRB is charged with the responsibility for coordinating internal and external auditing and monitoring efforts in order to ensure the protection of human subjects and compliance with federal regulations and IRB policies. The IRB has the authority to observe, or appoint a designee to observe, the informed consent process and the IRB approved research.
- 1.2 The IRB Chairperson may direct an experienced designee (e.g, NSMC Compliance and Business Integrity Department) to initiate periodic and/or directed audits when deemed necessary.
 - a) A periodic audit is a systematic method to audit a selection of IRB approved research at a frequency not to exceed every two (2) years.
 - b) A directed audit is an audit conducted in response to identified concerns (for-cause or result of a complaint).
- 1.3 Monitoring and/or auditing activities may include, but are not limited to the following:
 - a) Interviews with the Investigator and research study staff;
 - b) Review of progress reports from investigators;
 - c) Review of research records, including copies of signed consent forms;
 - d) Observation of the informed consent process;
 - e) Review of all correspondence between Investigator and IRB;
 - f) Review of advertisements and other recruiting materials;
 - g) Determination that all research-related procedures performed are as described in the IRB-approved protocol;
 - h) Determination that all protocol changes (modifications/amendments) were implemented only after IRB approval, except in circumstances to eliminate an immediate apparent hazard to participants.
 - i) Review projects to verify from sources other than the investigator that no unapproved changes have occurred since previous IRB review.
 - j) Other monitoring or auditing activities deemed appropriate by the IRB.

- 1.4 The results of any auditing or monitoring activity shall be reported in writing to the IRB Chairperson and Administrator. The IRB Chairperson shall determine the need for full IRB Committee review. The results will be placed on the agenda of the next regularly scheduled meeting for action as appropriate. In addition, all auditing and monitoring information will be maintained in the IRB study file and provided to the primary reviewer at the time of the next continuing review.
- 1.5 The Principal Investigator will be responsible for providing a written response to the audit including, but not limited to, a detailed corrective action plan with timelines.
- 1.6 If the auditing or monitoring of a research activity reveals that a human subject has been exposed to unexpected serious harm, such finding shall be reported in accordance with IRB Policy 020, *Unanticipated Problem and Adverse Event Reporting*. The finding and related study shall be placed on the agenda of the next regularly scheduled meeting for discussion and action.
- 1.7 The IRB may suspend or terminate research if the information gained during the monitoring or auditing process indicates that human subjects in a research project were exposed to unexpected serious risk or harm, or that the federal regulations or the policies of the IRB were not met (refer to IRB Policy 009, *Suspension or Termination of IRB Approval of Research*).

2. IRB Administrative Audits

- 2.1 The NSMC Compliance and Business Integrity Department, or designee, will conduct an audit of NSMC IRB activities on a regular basis, with the interval to be no longer than every two (2) years. The audit is used to measure the effectiveness and compliance of the IRB's administrative activities.
- 2.2 The IRB activities that may be audited include, but are not limited to, the following:
 - Proper use of expedited and exemption categories;
 - Timeliness of IRB responses and reviews;
 - Timeliness of continuing review of approved research;
 - Appropriateness of the approved informed consent form process and elements of informed consent;
 - Completeness of IRB minutes;
 - Situations involving unanticipated problems and/or suspensions or terminations of IRB approval;
 - Compliance with IRB policies and maintenance of policies with current regulations
- 2.3 The results of any IRB audit will be provided in writing to the NSMC IRB Chairperson and Administrator, who in turn will present the findings to the IRB committee, the NSMC Institutional Official, NSMC Chief Operating Officer, and NSMC President and CEO.
- 2.4 The NSMC IRB Chairperson and Administrator will be responsible for providing a written response to the audit including, but not limited to, a detailed corrective action plan with timelines.
- 2.5 The results of any IRB audit will be maintained in the IRB Office files as required per IRB Policy 014, *Records Requirements*.

3. Reporting

- 3.1 If the results of an audit, of either the investigator or the IRB, indicate serious or continuing non-compliance that is required to be reported to the Office of Human Research Protections and/or

the Food and Drug Administration, a report will be submitted in accordance with IRB Policy 026, *Investigations of Noncompliance*.

4. Continuous Improvement

- 4.1 To support continuous improvement when policy or procedure changes as a result of conducted audits, the NSMC Compliance and Business Integrity Department, or designee, may perform a follow-up review to help determine whether the existing processes remain effective.

V. RELATED POLICIES, REGULATIONS, AND REFERENCES

DHHS Regulations 45 CFR Part 46

FDA Regulations 21 CFR Parts 50, 56