

THE NORTH SHORE MEDICAL CENTER Institutional Review Board (IRB) POLICIES AND PROCEDURES	IRB Policy Number: 014.1
Title: <i>Record Requirements</i>	Page: 1 of 4
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I. PURPOSE

This policy defines the requirements for maintaining records by the North Shore Medical Center Institutional Review Board (NSMC IRB).

Federal regulations require IRBs to keep copies of all approved protocols on file and available for inspection by authorized representatives of the DHHS, the Office for Human Research Protection (OHRP) and the FDA. The IRB is also required to maintain files indicating documentation of all actions taken by the IRB, membership of the IRB and attendance records.

II. SCOPE

This policy applies to all activities of the NSMC IRB and all activities regarding research involving human subjects reviewed by the NSMC IRB. The determination of whether a proposed activity constitutes research involving human subjects is described in NSMC IRB Policy 027.

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)]

IV. PROCEDURE

1. IRB Meeting Minutes

1.1 The minutes of convened IRB meetings shall include the following:

- Voting members (or alternates) present;
- Voting members (or alternates) absent;
- Staff and guests, including consultants, present;
- Statement regarding review of the conflict of interest policy prior to start of meeting; and

For each human-subjects research activity and clinical investigation reviewed at the meeting:

- Action voted by the IRB;
- Number of votes for, against, and abstaining from voting;
- Members attending but not present for the discussion and vote;
- Notation that Investigators and study staff for a particular study have left the room for IRB discussion and vote;
- Recusals of voting members;
- Period of IRB approval, i.e., one year or less;
- Including, when applicable, additional protections for pregnant women, human fetuses and neonates, and for children;
- Summary of the discussion of controverted issues and their resolution;
- Modification required and/or additional information requested by the IRB; and
- Basis for requiring changes or disapproving the research.

1.2 Minutes shall be presented to the members for approval and provided to the Institutional Official (IO) of NSMC and, upon request, to IOs of other institutions who, by appropriate IRB Authorization Agreement, rely on the NSMC IRB for IRB review.

2. IRB Study File

2.1 The NSMC IRB Office shall maintain individual files of every research activity reviewed by the IRB, whether at a convened meeting or using expedited review, to include:

- All of the documents submitted with the research proposal for initial review including, but not limited to, the application form, protocol summary, detailed protocol, recruitment materials (letters, flyers, advertisements, etc.), consent form(s), drug/device brochures, application for funding (e.g., NIH or other federal grant), NIH cooperative group protocol, NIH cooperative group sample consent form, ancillary committee/department review, scientific evaluations, if any;
- Written reports from consultants to the IRB;
- Checklists and review documentation, including review forms signed by the IRB Chairperson or designated alternate(s);
- IRB-approved recruitment materials;

- IRB-approved consent forms;
- Progress reports, interim analyses, safety reports, DSMB/DMC reports;
- Reports of unanticipated problems involving risk to subjects or others;
- Proposed changes to the protocol and revised documents (amendments);
- Copies of all correspondence between the IRB and investigator;
- Continuing review submissions for review including, but not limited to application form, protocol summary, detailed protocol, recruitment materials, NIH progress reports; and
- Statements of significant new findings provided to subjects;
- Copies of any correspondence to OHRP and/or FDA regarding reports of unanticipated problems or noncompliance.

For exempt projects (refer to IRB Policy 008 *General Review Procedures* for definition and review process), the minimum items to be maintained in the file include:

- Research plan or summary
- Exemption determination review form citing the specific approved exemption category for the research.
- Signed IRB approval letter stating the specific category under which the study was determined to be exempt.

For studies designated to another IRB for review, at a minimum the NSMC IRB will maintain the initial documents submitted to the NSMC requesting designation and the letter granting designation of review.

3. IRB Membership Roster

- 3.1 The IRB Office will maintain documentation of IRB members in accordance with IRB Policy 004 *IRB Composition and Roster*.

4. IRB Policies and Procedures

- 4.1 The IRB Office will coordinate the creation of all NSMC IRB policies required to implement Federal regulations for protection of human subjects.
- 4.2 The IRB Office will review all policies on a biennial basis to determine if revisions are necessary to comply with changes in state or federal law, current practice or other NSMC or PHS policies.
- 4.2.1 If changes are required, the IRB Administrator will initiate the process to revise the policies. All changes will be documented on a change control form.
- 4.2.2 All policies will be reviewed by the IRB membership and approved by the IRB Chairperson.
- 4.2.3 Significant changes in IRB policies will also be reviewed by the NSMC IO. As needed, proposed policy changes also will be sent to other departments at NSMC, such as Legal or Compliance, for review and comment.
- 4.3 Upon finalization, all IRB policies will be placed on the NSMC IRB website. The IRB Office will retain previous versions of policies for reference.

5. IRB Electronic Database

- 5.1 The NSMC IRB utilizes the Partners Research Express (ReX) IRB electronic database for all active and terminated IRB studies with relevant information relating to the status of each protocol and IRB actions. This database is secured by restricted access to IRB administration only.

6. Format and Retention Period for IRB Records

- 6.1 All IRB records are maintained in hard (paper) copy with the exception of the IRB ReX database, which is in electronic format.
- 6.2 The IRB Office will retain minutes for at least six (6) years, and individual files of research activities shall be retained for at least six (6) years from completion of the research or closure of the file.
- 6.3 The IRB Office shall secure all records in lockable filing cabinets or storage rooms.

7. Access to IRB Records

- 7.1 All IRB records, in any format, are considered confidential and may be accessed only by authorized individuals or regulatory agencies as required by law.
 - 7.1.1 Access to IRB records is limited to the IRB membership, IRB staff, authorized IRB representatives, and officials of Federal and state regulatory agencies.
 - 7.1.2 In addition, IRB records may be reviewed upon request by the NSMC Compliance Officer, NSMC Board of Directors, NSMC Institutional Official and Partners HealthCare System Inc (PHS).
 - 7.1.3 All other access to IRB records is limited to those who have legitimate need for access, as determined by the IRB Office.
- 7.2 All records shall be accessible for inspection and copying onsite by authorized representatives of approved organizations or entities such as representatives of the sponsor, DHHS, OHRP, and when relevant, the NIH and FDA, during normal business hours.

V. RELATED POLICIES, REGULATIONS, AND REFERENCES

- IRB 004 IRB Composition and Roster
- IRB 008 IRB General Review Procedures

- DHHS Regulations 45 CFR Part 46
- FDA Regulations 21 CFR Parts 56