

<b>THE NORTH SHORE MEDICAL CENTER Institutional Review Board (IRB) POLICIES AND PROCEDURES</b>	<b>IRB Policy Number:</b> 015.1
<b>Title:</b> <i>Initial Review of Research</i>	<b>Page:</b> 1 of 4
<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
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## I. PURPOSE

This policy defines the procedures for the initial review of research by the North Shore Medical Center Institutional Review Board (NSMC IRB).

## II. SCOPE

This policy applies to all applications regarding research involving human subjects submitted to the NSMC IRB. All protocols must meet the criteria required under Federal regulations 45 CFR 46.111 and FDA requirements 21 CFR 56.111. It is the responsibility of IRB members to assure that approved protocols meet these criteria. 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)]

**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

##### 1. Required Application Materials

- 1.1 Principal Investigators (PI) relying on the NSMC IRB for review of human-subjects research are required to complete the applicable application form and submit all necessary information and documents for review to the NSMC IRB. For initial applications, the items required for submission are listed in the *NSMC IRB New Protocol Submission Checklist*.
- 1.2 All investigators and research staff listed on the application must complete the Collaborative Institutional Training Initiative (CITI) basic or refresher course (as applicable) as per IRB Policy 021 "*Human Subjects Protections Training Requirement*" prior to submission of the application to the NSMC IRB.
- 1.3 For industry-sponsored studies only, upon receipt of an application an invoice for the applicable IRB fee (\$2000 for convened board review, \$1000 for expedited review) will be sent to the Sponsor and must be paid before the IRB will issue an approval letter.
- 1.4 For industry-sponsored studies only, contracts and budgets must be reviewed and approved by the appropriate NSMC institution official or designee prior to the release of an IRB approval letter. The NSMC IRB will coordinate with the appropriate NSMC institution official or designee to determine when the review and approval process has been completed.

##### 2. Submission Processing and General Review Procedures

- 2.1 Refer to IRB Policy 008 IRB *General Review Procedures* for details regarding processing of submissions, determination of type of review (i.e., exempt, expedited or full board), general review process, determinations and communications.

##### 3. Distribution of Materials

- 3.1 For review of initial applications at convened IRB meetings, all members attending the meeting shall receive a copy of the required forms, protocol summary, any advertisements/recruitment materials, and the informed consent form submitted by the investigator. The primary reviewer will receive the above plus a copy of the detailed protocol and where applicable the drug/device brochure and the application for funding (e.g., NIH grant). These documents are available to all members upon request.

3.2 For review of initial applications via expedited review, the IRB Chairperson or designee will receive all documents for review.

#### **4. Criteria for Review and Approval and other IRB Considerations**

4.1 When reviewing initial applications, the criteria for IRB approval at 45 CFR 46.111 and when applicable 21 CFR 56.111 must be met to approve or recommend approval of the application. Specifically, the IRB must find that:

- a) Risks to subjects are minimized:
  - i) By using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
  - ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- b) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.
- c) Selection of subjects is equitable.
  - i) In making this assessment the IRB will take into account the purpose of the research and the setting in which the research will be conducted. The IRB will evaluate the recruitment, enrollment, and payment procedures for participants to determine that the Investigator has access to a population that would allow recruitment of the required number of participants, and ensure that undue coercion will not be used. The IRB will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.
- d) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by appropriate local, state and federal regulations.
- e) Informed consent will be appropriately documented in accordance with and to the extent required by the regulations.
- f) When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.
- g) When appropriate, there are adequate provisions to protect the privacy of subjects, and to maintain the confidentiality of data.

In addition, when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study and in the IRB review process, to protect the rights and welfare of these subjects.

4.2 The NSMC IRB will determine whether a research activity requires more than annual review to ensure the protection of the rights and welfare of research subjects. The IRB will consider the nature of the study, the degree of risk involved and the vulnerability of the study subject population in determining the approval period and review interval. The review interval will be communicated to the Investigator in writing.

- 4.3 Investigators are required to provide the NSMC IRB with all relevant information regarding the conduct of the research and fulfill all requirements for prompt reporting to the IRB of unanticipated problems involving risks to subjects or others. The NSMC IRB may request independent verification of information submitted by an investigator in the following situations, for example: 1) complex projects involving unusual levels or types of risk to subjects; 2) research being conducted by persons who have previously failed to comply with all regulations or requirements of the NSMC IRB; 3) as a result of information disseminated via regulatory authorities or other sources; 4) studies in which substantial segments of the project are conducted off site by collaborators, or in which NSMC investigators conduct research off site and 5) discrepancies in application materials.

## V. RELATED POLICIES, REGULATIONS, AND REFERENCES

IRB 008 IRB General Review Procedures  
IRB 021 Human Subjects Protections Training Requirement  
Form *NSMC IRB New Protocol Submission Checklist*

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