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| <b>THE NORTH SHORE MEDICAL CENTER<br/>Institutional Review Board (IRB)<br/>POLICIES AND PROCEDURES</b> | <b>IRB Policy Number:</b> 027.0   |
| <b>Title:</b> <i>Human Subjects Research Determination</i>   | <b>Page:</b> 1 of 3   |
| <b>Written by:</b> _____<br>Laura W. Knight, MPH; Sr. IRB Administrator                                | <b>Date this issue:</b> December 2008<br><b>Previous issue(s):</b> None |
| <b>Approved by:</b> _____<br>Charles Bockoff, MD; Chairman, NSMC IRB                                   | <b>For further information contact:</b><br>IRB office 781-477-3678      |

## I. PURPOSE

This policy defines the process followed by the North Shore Medical Center Institutional Review Board (NSMC IRB) for determining whether an activity meets the definition of human subject research based on Federal regulatory definitions, 45 CFR 46.102(d), 21 CFR 50, or 21 CFR 56.

## II. SCOPE

Per IRB Policy 002, *IRB Jurisdiction and Authority*, 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. "Human research" means any activity that under the DHHS regulations represents "research" that involves "human subjects," or any activity that under FDA regulations represents a "clinical investigation" that involves "human subjects".

## 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. The Investigator may utilize the NSMC IRB *Research Determination Worksheet* to initially review the project for human participants and/or whether the project meets the definition of research. This worksheet is a tool and submission to the NSMC IRB is not required.
  - 1.1 If the *Research Determination Worksheet* indicates that the project does not involve human participants and is not considered research, the Investigator may initiate the project without IRB review.
  - 1.2 If the *Research Determination Worksheet* indicates that the project involves humans as participants and/or if the definition of research is met, the Investigator should complete and submit an applicable application and support documents to the IRB for review and approval per IRB Policy 015, *Initial Review of Research*.
    - 1.2.1 If the *Research Determination Worksheet* indicates that the project involves humans as participants and/or if the definition of research is met but the Investigator believes the research is exempt, the Investigator must submit information to the IRB for this determination to be made by the IRB Chairperson (refer to IRB Policy 008 *IRB General Review Procedures*). Only the IRB can make a determination of exemption.
2. If the Investigator has unresolved issues after completing the *Research Determination Worksheet*, or wishes to receive a written determination from the IRB, the Investigator has the option of submitting the *Research Determination Worksheet* to the IRB.
  - 2.1 The *Research Determination Worksheet* is directed to the IRB Chair and/or the IRB Administrator for determination. The IRB Chair and/or Administrator may contact the Investigator for additional information as needed.
  - 2.2 If the IRB Chair and/or Administrator determines that the project constitutes 'human research', the reviewer will also determine whether or not the project may be exempt from IRB review (refer to IRB Policy 008 *IRB General Review Procedures*). The IRB Chair must sign off on any determination of exemption.

*Note: The NSMC IRB retains the right to determine when research proposals that may otherwise meet the DHHS criteria for exemption should be reviewed by the IRB through an expedited process or at a convened meeting.*
  - 2.3 The IRB will provide the Investigator with written documentation of its determination of whether the activity requires submission to the IRB. The original correspondence and resulting determination is kept on file in the IRB.
3. Other Applicable Standards for Not-Human Participant or Non-Research Projects
  - 3.1 All projects conducted at NSMC shall be subject to other standards of review as determined by NSMC and/or Partners policy and/or procedure.

- 3.2 Any change to a research project deemed not-human participant or non-research shall be re-reviewed to determine whether the change alters the original determination of not-human participant or non-research.

## **V. RELATED POLICIES, REGULATIONS, AND REFERENCES**

IRB 002 Jurisdiction and Authority  
IRB 008 General Review Procedures  
IRB 015 Initial Review of Research

NSMC Research Determination Worksheet

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