

<b>THE NORTH SHORE MEDICAL CENTER Institutional Review Board (IRB) POLICIES AND PROCEDURES</b>	<b>IRB Policy Number:</b> 007.1
<b>Title:</b> <i>Research Conflicts of Interest</i>	<b>Page:</b> 1 of 5
<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
<b>Approved by:</b> _____ Charles Bockoff, MD; Chairman, NSMC IRB	<b>For further information contact:</b> IRB office 781-477-3678

## I. PURPOSE

The purpose of this policy is to ensure the objectivity of human-subjects research, and to avoid actual or perceived conflicts of interest in such research, by defining the process for consideration of conflicts of interest in the review of human-subjects research and clinical investigations under the jurisdiction of the North Shore Medical Center (NSMC) Institutional Review Board (IRB).

In cases when the NSMC IRB determines that there is a financial conflict of interest that could affect or otherwise be relevant to the research, the IRB must determine that the conflict is either eliminated or appropriately managed to ensure that the rights and welfare of human subjects are protected.

## II. SCOPE

This policy applies to human-subjects research and clinical investigations reviewed by the NSMC IRB that involve any of the following:

- (1) For-profit sponsor or funding source;
- (2) A marketed drug, device, or other technology, or a drug, device or other technology in development; or
- (3) A new technology, software or therapeutic approach.

The IRB may choose to delegate portions of the collection, review, analysis, and proposed resolution of any particular situation to other institutional officials, subject always to the final approval of the IRB of the resolution.

This policy applies to investigators and study staff as well as members of the NSMC IRB (including *ad hoc* or consultant reviewers who are not IRB members but sometimes are asked to review a project because of their expertise).

## 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)]

#### Other definitions:

Generally, a conflicting interest includes (1) participation in the project; (2) a financial interest as defined below; and/or (3) non-financial interests.

#### **Financial Interest:**

An interest in a company consisting of: (1) any stock, stock option or similar ownership interest in the business, but excluding any interest arising solely by reason of investment in a company by a mutual, pension, or other institutional investment fund over which you do not exercise control; or (2) receipt of, or the right or expectation to receive, any income from such business (or from an agent or other representative of such business), whether in the form of a fee (e.g., consulting), salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty derived from the licensing of technology, rent, capital gain, real or personal property, or any other form of compensation, or any combination thereof. For the purposes of this policy, the term financial interest includes, but is not limited to: (i) royalties presently being received; (ii) the right to receive royalties in the future; and (iii) licensing fees or milestone payments; including any of the foregoing (i)-(iii) which are paid or payable to the individual directly or through institutional revenue-sharing policies.

#### **Family member:**

A spouse, minor/dependent children, and other persons living in the same household.

**Non-financial interests** – these are varied but for practical purposes a few examples are given:

The individual or a family member of the individual:

- is involved in the conduct of the research;
- is a direct supervisor or trainee of the researcher(s)
- is related to a researcher whose protocol is under consideration
- has a prominent role in a directly competing research team or product
- has a close personal relationship with a researcher, or for other reasons feels unable to render a fair and unbiased review.

#### IV. PROCEDURE

All information pertaining to disclosed conflicts of interest will be kept confidential to the extent allowed by this policy.

##### 1. Investigators and Study Staff

- 1.1 All investigators and other study staff (including research coordinators, data coordinators, etc., that are listed on IRB submissions) participating in the conduct of human-subjects research or clinical investigations must complete and submit with each new protocol to the IRB the *NSMC Research Financial Disclosure Form* when the research/investigation involves any of the following:
  - (1) For-profit sponsor or funding source;
  - (2) A marketed drug, device, or other technology, or a drug, device or other technology in development; or
  - (3) A new technology, software or therapeutic approach.
- 1.2 Investigators and study staff must report to the IRB any changes to the information provided in the *NSMC Research Financial Disclosure Form*, as soon as possible, but in no event later than thirty (30) days after the change.
- 1.3 At the time of continuing review, investigators and study staff must certify on the *NSMC Continuing Review Application Form* that either there are no changes to the most current information provided regarding conflicts of interest or complete an updated *NSMC Research Financial Disclosure Form*.
- 1.4 Completion and submission of the *NSMC Research Financial Disclosure Form* does not take the place of the obligation of staff to fill out other periodic conflict of interest disclosure forms that are required by either NSMC or Partners HealthCare System, Inc. (PHS).
- 1.5 The IRB Administrator or designee shall review the completed *NSMC Research Financial Disclosure Form* and shall refer those with disclosed financial interests to the IRB Chairperson or designee for review.
- 1.6 The IRB Chairperson shall review any disclosed financial interests of individuals that are not prohibited by the PHS Code of Conduct and Conflicts of Interest Policy, or other applicable policies, and shall make recommendations to the IRB relating to the disclosed financial interest. The recommendations may include, but need not be limited to, the following options: that the disclosed financial interest is:
  - (a) Not acceptable (in which case the financial interest must be divested or other action taken);
  - (b) Acceptable with some form of management (such as disclosure, restrictions on the activities of the investigator, or such other form as determined appropriate); or
  - (c) Acceptable without any need for management.
- 1.7 The IRB Administrator and/or Chairperson or designee may request information on and review any other financial interests that could affect or otherwise be relevant to a specific research protocol.
- 1.8 In the course of reviewing the disclosed financial interest, the IRB Chairperson or Administrator or designee may consult with the NSMC President/CEO, NSMC Compliance Officer, NSMC Legal Counsel, or other individuals or committees as necessary, as well as establish whatever subcommittee of the IRB that may be useful to assist in rendering a determination. If a referral to the NSMC President/CEO, NSMC Compliance Officer, NSMC Legal Counsel, or other individual or committee is made, the IRB shall be informed of the outcome of the review. Full approval of the IRB shall be contingent upon the outcome of the review/referral process. The

NSMC IRB has final authority to make decisions regarding management of the conflict and the conduct of the research.

- 1.9 The NSMC IRB shall review the recommendations of the IRB Administrator and Chairperson and shall determine whether the recommendations are acceptable. If not, the IRB may determine that other action needs to be taken.
- 1.10 The Investigator or study staff member with disclosed financial interests, and other pertinent institutional officials as appropriate, shall be notified of the determinations of the IRB with respect to disclosed financial interests as part of the IRB review notification process.
- 1.11 During the process of overall review of a research application (including review of protocol, informed consent form, protocol summary, agreements and contracts with Sponsor, etc), the NSMC IRB shall consider whether other non-financial interests exist that may directly and significantly affect, or have the appearance of directly and significantly affecting, an investigator's or study staff member's professional judgment in conducting the research. The Investigator or study staff member shall be notified of the determination of the IRB with respect to non-financial interests as part of the IRB review notification process.

## 2. IRB Members

- 2.1 Upon receipt of materials before a meeting, IRB members shall review the agenda for initial or continuing review for any (zero threshold) financial or non-financial interests. Any interests should be disclosed to the IRB Chairman and Administrator in advance of the meeting when possible. At the beginning of each IRB meeting, members will also be reminded of the conflicts policy and should disclose any previously unreported interests at that time.
- 2.2 Any IRB member with a conflict of interest in a project:
  - In full committee, must leave the room during the discussion of the project and the related vote, except if the member is providing information at the IRB's request. The meeting minutes will document the recusal (*i.e.*, the temporary absence of the IRB member during the deliberation and vote on the project with respect to which the member has a conflict). Recused members are not counted towards the quorum requirement; therefore, if a quorum of the membership is not present for the review of any protocol, no vote is taken and the protocol is held over for review at the next convened IRB meeting.
  - Will not be allowed to perform expedited review or make determinations of exemption for that protocol.
- 2.3 All IRB members will be notified and reminded of this policy.
  - COI policy will be part of new IRB member orientation
  - IRB members receive reminders of the COI policy with the receipt of all meeting materials
  - Members will be directed to the policy, which appears on IRB members' agenda documents.
- 2.4 When performing expedited review, the IRB reviewer will promptly report to the IRB Chairperson and Administrator any financial or non-financial interests with the project. Upon determination of a conflict, the project will be reassigned to another reviewer.
- 2.5 Consultant reviewers will receive a copy of this policy with materials for the project they are reviewing and will be asked to disclose any financial or non-financial interests to the IRB Chairperson and Administrator who will determine management. *Consultant* reviewers who have a determined conflict of interest regarding a specific protocol will not be allowed to review the protocol.

- 2.6 NSMC projects: An IRB member may not consult for a Business to assist it in shepherding a project through the IRB process when the project will be performed within NSMC.

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

IRB Policy #002	IRB Jurisdiction and Authority
IRB Policy #004	IRB Composition and Roster
Form	NSMC Research Conflict of Interest Form