Policy for: Conflict of Interest for Clinical Trials Research	
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JUNE E. NYLEN CANCER CENTER
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CONFLICT OF INTEREST POLICY FOR CLINICAL TRIALS RESEARCH

Rationale for the Conduct of Policy

Siouxland Regional Cancer Center (SRCC) believes it is of utmost importance that activity involving research be conducted above suspicion and reproach. Scientific credibility and the acceptance of findings depend on the integrity and objectivity of persons conducting the research, analyzing the data and reporting the outcome. Perceptions of bias may cast doubt on study results. More than a purely scientific interest in the outcome of clinical investigations could potentially be attributed to:

- Professional interest – one has a substantial role in the development of the product or technology being evaluated.
- Ongoing affiliation – with the organization holding the patent to or license for development or sale of the research product.
- Proprietary or pecuniary – material interest in a product or technology, where the sale of such will provide a financial gain or increased support of research.

Therefore, a Conflict of Interest Disclosure Form (and/or Financial Disclosure Form) will be collected upon initial investigator registration (or rostering) and then annually (or more often if a new potential significant conflict is identified) from investigators. Having significant financial interests are allowed but must be disclosed. This policy provides guidance to identify and manage potential conflicts in a proactive manner. Several research institutions may also require investigators to complete financial disclosure specific to the research being conducted. It is a requirement for SRCC investigators to comply with those policies as well. It is recognized that other research institutions may have policies that are more or less stringent than SRCC's policy.

For United States Public Health Service (PHS)-sponsored research, SRCC's policy is based on the requirements of 42 CFR Part 50, Subpart F. The National Institutes of Health (NIH) requires grantees and investigators to comply with the requirements of 42 CFR Part 50, Subpart F, "Promoting Objectivity in Research." That subpart promotes objectivity in research by establishing standards to ensure that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will not be biased by any conflicting financial interest of an investigator.

Definitions

<u>Investigator Definition</u>

Investigator means the project director or principal investigator and any other person, *regardless of title or position*, who is responsible for the *design, conduct, or reporting of research funded by the PHS* (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants. SRCC considers the role, rather than the title, of those involved in research and the degree of independence with which those individuals work. When the definition of investigator is limited to titles

or designations (e.g., to principal investigators, key personnel, faculty) the risk that an unidentified FCOI may compromise the research enterprise increases.

In addition, the Investigator's spouse and dependent children are not included in the definition of "Investigator" under the 2011 revised regulation; however, they are referenced in the definition of "Significant Financial Interest" because the Investigator must also disclose Significant Financial Interests of his/her spouse and dependent children. (See definition of Significant Financial Interest.)

Research Definition

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (*e.g.*, a published article, book or book chapter) and product development (*e.g.*, a diagnostic test or drug). As used in 42 CFR Part 50, Subpart F, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Significant Financial Interest Definition

Significant financial interest means:
(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
(i) With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (*e.g.*, consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
(ii) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (*e.g.*, stock, stock option, or other ownership interest); or
(iii) Intellectual property rights and interests (*e.g.*, patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C.1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated

with an Institution of higher education. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

The SRCC COI Review Committee

The Executive Director, Local Principal Investigator for PHS funded research, Director of Research, and Compliance Manager will comprise the Conflict of Interest Committee. The Director of Research will serve as Chair of the COI Committee (the Committee).

Implementation and Training

The Research Administrative Coordinators will solicit and review financial disclosure statements for investigators as part of the process of investigator registration to the NCI, and cooperative groups. Disclosure Forms may also be required for other clinical trials that are non-NCI/PHS funded (i.e., industry-sponsored trials) and the Administrative Coordinators will distribute initial and subsequent documents to maintain compliance as required by the study sponsor. (Also, see Enforcement section below.)

Administrative Coordinators will notify the Director of Research of responses that indicate a potential significant conflict of interest. The Director of Research will notify the Committee.

The Committee will provide formal determination toward the significance of the reported potential conflict. If a significant conflict of interest is determined to be present the person reporting the significant conflict of interest will be notified in writing. The Investigator reporting the conflict of interest may exercise the right to eliminate, decrease or maintain the equity that creates the conflict. The Director of Research has the responsibility to report significant conflicts to the PHS.

Training on this policy and 42 CFR Part 50, Subpart F (the code) is required every four years, and when changes occur. Training is accomplished by self review of this policy and the then current code. Specific changes in the code that require changes to this policy will be outlined in the Revisions and Reviews

section of this policy. The code is referenced as Exhibit 1 of this policy and will be attached for self review as needed or upon request.

Inclusion Criteria

Because of their roles in research activities, this policy will require Physician Investigators, CRAs, and persons that obtain study participant consent to complete the SRCC COI form on an annual basis.

The following persons may be required to submit disclosure depending on various institutions' policy.

- Active personnel with a M.D. degree.
- Active personnel with a D.O. degree.
- Active non-physicians holding the role of a study chair or co-chair.
- Those that the Principal Investigator, or Review Committee identify as needing to disclose.
- Others that may be required by individual membership research base policies or other study sponsors.

Disclosure Criteria

Persons identified under this policy's Inclusion Criteria shall provide disclosure as it relates to self, spouse, dependent children, or individuals with whom the member maintains a relationship involving shared income or assets, or as required by research bases and study sponsors.

It is mandatory that persons described under Inclusion Criteria initiate and submit an updated disclosure form between scheduled annual updates should a situation occur that places a member, self, spouse, dependent children, or individuals with whom the member maintains a relationship involving shared income or assets into any of the categories of potential significant conflict of interest as defined by the research base or study sponsor.

Sanctions

Investigators with a conflict of interest may be disqualified from:

- Appointment to a clinical trial leadership role (investigator, sub-investigator, study chair, co-chair or statistician)
- Authorship privileges (publication &/or presentation)

Other sanctions may also be invoked by a study sponsor's reviewing committee including, but not limited to, prohibiting activities related to investigation(s) of a specific research product.

Enforcement

Regarding disclosure forms that do not report a potential significant conflict of interest, the initial and updated disclosure forms will be submitted by the Research Administrative Coordinators or Study

Coordinator to the respective research base when required. Failure by persons identified under this policy's Inclusion Criteria to disclose potential conflict of interest activities may result in the loss of privilege to participate in research activities at SRCC. The Local Principal Investigator (or other physician designated by the PI and approved by the Executive Director), the Executive Director, the Director of Research, and the Compliance Manager comprise the committee to review and implement the sanctions that are imposed by the respective research bases as needed.

Public Information

SRCC will post this policy on its website for the June E. Nylen Cancer Center, and disclose significant financial conflicts of interest on said website or make written disclosure of conflict available within 5 business days.

Revisions and Reviews

It is expected that this policy may require revisions from time to time. Investigators will receive education on revisions and may be asked to complete a disclosure form at the time of the revision if needed. This section will summarize revisions.

May 22, 2015 - First version for June E. Nylen Cancer Center.
July 10, 2018 - First version for June E. Nylen Cancer Center reviewed. The section of the policy titled "Revisions" has been changed to "Revisions and Reviews". A reference to this section was updated to state Revisions and Reviews. Version number and date updated. Part 1 of the FCOI form no longer requires address for employees of Siouxland Regional Cancer Center, and the Role section changed the term "Investigator" to "Sub-Investigator" since, by definition, all personnel required to complete this form are Investigators. There are also formatting changes.
July 20, 2020 – reviewed. Removed role of "Submits data/CRFs" from the Financial Conflict of Interest Form Part 1 as the role is part of "Data Management." Added "Study Coordinator" to the roles. Text in Note on signature page edited as:
NOTE: IF YOU ANSWERED "YES" TO ANY PARTS OF ~~THE~~ QUESTIONS 1 – 3 ABOVE, PLEASE COMPLETE PART II~~.~~; OTHERWISE, **STOP**.
Formatting changes.

Addendum for Industry-Sponsored Clinical Trials

It is recognized that industry sponsors may also require disclosure of financial conflicts of interest. Industry sponsors may have an additional form, and different reporting guidelines and definitions related to conflicts of interest. Therefore, the industry sponsors will also be notified of information disclosed and when conflicts or changes are reported by investigators. Sanctions and enforcement will be carried out in accordance with the policy applicable to PHS funding described above. In cases of significant conflicts with industry-sponsored studies, the sponsor or sponsor's representative will be notified by the Chair of the COI review committee.

Attachment

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Financial Conflict of Interest Form Parts I and II

Exhibit 1

42 CFR Part 50, Subpart F

If link does not open, copy/paste to your web browser:
http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=42:1.0.1.4.23#sp42.1.50.f