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| <b>SOP: GA 104</b><br><b>Version No:</b><br><b>Effective Date: 01/01/07</b> | <b>CONFLICT OF INTEREST</b> | <b>Supercedes Document</b><br><b>Dated:</b> |
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## 1. POLICY

In the environment of research, openness and honesty are indicators of integrity and responsibility, characteristics that promote quality research and can only strengthen the research process. Therefore, conflicts of interest for IRB members or research investigators should be eliminated when possible and effectively managed and disclosed when they cannot be eliminated.

### Specific Policies

#### 1.1 Definition of a COI

*Investigator Conflict of Interest (COI)* is any situation in which financial or personal interests may compromise or appear to compromise an investigator's professional judgment in conducting or reporting research.

*IRB Member Conflict of Interest (COI)* is any financial interest or scholarly or social commitment or relationship that would impair the ability of the reviewer to make fair and impartial judgments about a research application.

Conflicts of interest may occur when:

- IRB member, investigator, or member of his/her immediate family has or will receive from the sponsor of the research financial or other form(s) of compensation; or
- IRB member, investigator, or member of his/her immediate family have a significant financial interest in the company/agency/firm that is sponsoring the research; or
- IRB member, investigator, or member of his/her immediate family discloses a conflict of interest to the FDA or other agency.

**Immediate Family:** IRB member or investigator's spouse or domestic partner, minor children, and anyone who resides with the IRB member or investigator or who is the IRB member of investigator's dependent for tax purposes. This will usually be a smaller group of people than the IRB members or investigator's relatives.

**Significant Financial Interest:** Anything of monetary value, including but not limited to, salary or other payment for services (e.g., consulting fees or honoraria); equity interests (e.g. stocks, stock options or other ownership interests); and intellectual property rights (e.g. patents, copyrights and royalties from such rights).

Questions regarding COI may be referred to the Corporate Compliance Department at Sparrow Health System.

#### 1.2 Disclosure and Documentation of Financial Interest and COI

##### **IRB Member COI:**

No regular voting or alternate member of the IRB may participate in the initial or continuing review of any research project in which the member has a COI, except to provide information as requested.

It is the responsibility of each voting member or alternate member of the IRB to disclose any COI in a study submitted to the IRB and to recuse him or herself from

deliberations and voting during the meeting. The IRB member will be asked to leave the meeting room during the discussion and voting on a proposal where there is COI. The IRB staff will record in the minutes any identified COI.

The procedures for recusal of IRB members, including the Chairperson, from deliberating/voting on all protocols for which there is a potential or actual financial conflict of interest are detailed in the SOP FO 303, IRB Meeting Administration. Each IRB member and alternate will be asked to complete an IRB Member Recusal Agreement (GA 104-A) that will be retained in the ORCO administrative office.

***Investigator COI:***

Each investigator shall disclose all “significant financial interests” on the application for initial IRB review and approval that would appear to be directly or indirectly affected by the research activities funded. The term “significant financial interest” is defined above, and does not include:

1. salary, royalties, or other remuneration from the applicant institution;
2. any ownership interests in the institution, if the institution is an applicant under the Small Business Innovative Research (SBIR) program;
3. income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
4. income from service on advisory committees or review panels for public or nonprofit entities;
5. an equity interest that when aggregated for the Investigator and his/her immediate family, meets one or the other of the following tests: Does not exceed **\$10,000** in value as determined through reference to public prices or other reasonable measures of fair market value or does not represent more than a five percent ownership interest in any single entity; or
6. salary, royalties or other payments that when aggregated for the Investigator and his/her immediate family over the next twelve months, are not expected to exceed **\$10,000**.

The investigator must disclose whether he/she or members of his/her immediate family receives financial or other compensation from the study sponsor and/or whether the investigator or members of their immediate families have a significant financial interest in the sponsoring entity. If the answer is “yes” to either question, the investigator must (1) provide a description of the relationship between the investigator and/or immediate family with the sponsor of the research, (2) include a statement in the informed consent form that addresses the conflict of interest, or (3) state why such a statement in the informed consent is not necessary for the protection of human subjects.

If an investigator COI develops after IRB approval, the investigator should promptly notify the IRB Administrator and/or IRB Chair, submit the change as an amendment (revision) to the approved protocol and include a revised consent form including a statement addressing any potential conflict of interest.

Each potential conflict will reviewed on an individual basis. The IRB may require that conflicts be disclosed in the informed consent, that the investigator recuses him/herself as the principal investigator, or from the study entirely.

COI in this context is different from the Sparrow Hospital associate Conflict of Interest policy.

## **2. SCOPE**

These policies and procedures apply to all IRB members, Investigators, OROC staff, and the Institutional Official (IO).

## **3. RESPONSIBILITY**

The IRB Administrator will place the application or amendment/revision on the upcoming IRB agenda for discussion by the IRB.

The IRB will evaluate whether the conflict of interest will affect the rights and welfare human subjects participating in the study. Evaluation considerations may include whether disclosure in the consent form is adequate to protect human subjects or if additional safeguards are needed. If the IRB determines that a conflict of interest could affect the rights and welfare of participants, then the conflict of interest must be eliminated or a management plan must be implemented so that the rights and welfare of participants are not affected by the interest.

The IRB Chair notifies Corporate Compliance of IRB determinations of COI that may affect the rights and welfare of participants. Corporate Compliance develops a management plan and informs the IRB. The IRB has the authority to approve the research, to require modifications that incorporate the Corporate Compliance management plan and/or additional IRB determined modifications, or to not approve the research. Corporate Compliance may not approve the research if it has not been approved by the IRB.

The IO, or designee, is responsible for articulating and enforcing the conflict of interest policy (COI) at Sparrow Health System. The IO has the authority to determine when COI exists as defined by institutional policy, and to refer to Corporate Compliance, Human Resources or the Medical Staff for enforcement of disciplinary action in the event that COI is not disclosed.

The IRB Administrator is responsible for monitoring the COI status and disclosures of IRB members.

The IRB Chairperson (or designee) is responsible for identifying COI disclosures before beginning every IRB meeting.

The IRB Administrator is responsible for documenting all COI disclosures in IRB meeting minutes.

## **4. APPLICABLE REGULATIONS AND GUIDELINES**

21 CFR 46.103, 107

21 CFR 56.107

21 CFR 54 (as reference)

FDA Information Sheets, FAQs, Section II, question 12

OHRP Draft Guidance on Financial Relationships 3/31/03

## **5. REFERENCES TO OTHER APPLICABLE SOPs**

This SOP affects all other SOPs.

## **6. ATTACHMENTS**

GA 104-A IRB Member/SHS Recusal Agreement

## 7. PROCESS OVERVIEW

The IRB Administrator and/or IRB Coordinator reviews each protocol submitted for potential of COI prior to the IRB meetings.

If an undisclosed COI is suspected, individuals submitting the study will be asked to confirm or deny the potential COI. In the event a COI is discovered the process in this policy will be come active. If at any time a purposely undisclosed COI is discovered the IO will be informed immediately and appropriate disciplinary action will be taken in accordance with the Sparrow Health System's Medical Staff and Administrative Policies and Procedures.

## 8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

| Who  | Task   | Tool                                    |
|--|--|---|
| <i>IRB Members</i>   | Disclose all financial and professional COI to IRB Administrator when joining the IRB, and periodically update that information. | IRB Member Recusal Agreement (GA 104-A) |
| <i>IRB Members</i>   | Recuse self from IRB deliberations where a COI exists or may appear to exist at beginning of meeting.                            |   |
| <i>IRB Administrator/<br/>IRB Coordinator</i>                | Document all COI disclosures in IRB meeting minutes.   |   |
| <i>IRB Coordinator</i>                                       | Maintain documentation of IRB member COI via disclosure forms and meeting minutes.   |   |
| <i>IRB Chairperson<br/>IRB Administrator<br/>IRB Members</i> | Ensure that IRB members with a COI do not participate in IRB deliberations subject to their COI disclosures.                     |   |