1 PURPOSE

1.1 This guidance establishes the methodology by which (a) the Sharp HealthCare (SHC) Institutional Review Board (IRB) will require the reporting of personal and institutional financial interests of researchers and research staff, (b) the IRB, directly or through a subcommittee and consultants, shall evaluate these reports for potential conflicts of interest that may foreseeably affect the ability of the reporting researchers or research staff to appropriately conduct human use research, and (c) the IRB will determine the type and degree of compensating controls indicated by the circumstances.

1.2 The guidance begins when Financial Disclosures are submitted to the SHC IRB.

1.3 This guidance ends twelve (12) months after the research study is closed by the SHC IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 If applicable, previous versions available in Human Research Protection Program Change Log.

3 POLICY STATEMENT

3.1 *Investigators* seeking approval to conduct research within the SHC system are required to disclose any *Significant Financial Interests* relating to their proposed research.

3.2 Covered Individuals:

3.2.1 Investigator – 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, which may include, for example, collaborators or consultants.

3.2.2 Family Members – an Investigator must also disclose significant financial interests of certain family members, including his/her spouse and dependent children.

3.3 Financial Interests: Related Definitions:

Financial Interest – anything of monetary value, whether or not the value is readily ascertainable.

3.3.1 Significant Financial Interest (SFI) –

3.3.1.1 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:

3.3.1.1.1 With regard to any publicly traded entity, an SFI 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 the 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;

3.3.1.1.2 With regard to any non-publicly traded entity, an SFI 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 Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

3.3.1.1.3 Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

3.3.1.2 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. Any travel disclosure required under this section should include the purpose of the trip, identity of the sponsor or organizer, the destination, and the travel duration.

3.3.1.3 The term SFI **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; 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.

3.3.2 Financial Conflict of Interest (FCOI) – Any SFI that has the potential to significantly and directly affect the design, conduct, or reporting of research.

3.4 Disclosure does not imply the existence of an actual or potential conflict of interest. The existence of a conflict of interest based on a SFI is determined by the IRB, or a designated subcommittee, taking into consideration any input from the SHC Vice President of Corporate Compliance or attorneys from the SHC Legal Affairs Department.

3.5 If the IRB or its subcommittee determines that an FCOI exists, they will determine whether the conflict may be effectively managed, or whether participation in the related study is contraindicated. In the event that effective management appears possible, the affected investigator will be asked to propose a plan to manage, mitigate, or remove the FCOI. The plan will be submitted to the IRB for review and approval, and IRB may propose additions or modifications to the management plan, which will be reviewed by investigator and incorporated into any final management plan. Investigator will be required to sign the management plan. In the judgment of the IRB committee, the study site monitor may also be required to sign the management plan if the IRB determines that it would aid in the effective oversight and management of the FCOI. The IRB will monitor the ongoing compliance of investigators or research staff with this management plan.

3.6 The evaluation and management of conflicts of interest will not vary by source of funding or regulatory oversight.

3.7 FCOI Training:

3.7.1 The IRB and the Center for Research are responsible for making sure that each investigator is informed of SHC's policy on financial conflicts of interest, the

responsibilities regarding disclosure of SFI, and when required, the necessity that each researcher complete IRB-approved training regarding these requirements.

3.7.2 Investigators conducting studies funded by the Public Health Service (i.e., NIH, FDA, CDC, etc.) are required to complete an IRB-approved FCOI training module as follows:

3.7.2.1 Initially when they first begin such a study (before draw-down of funds) and at least once every four (4) years thereafter.

3.7.2.2 Immediately when:

3.7.2.2.1 FCOI policies are revised in a manner that changes researcher requirements;

3.7.2.2.2 A researcher is new to the organization; and

3.7.2.2.3 A researcher is non-compliant with FCOI policies and procedures.

3.7.2.3 The NIH approved FCOI Training Module can be found at http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm

4 RESPONSIBILITIES

4.1 IRB staff and the IRB committee or designated sub-committee are responsible for evaluating SFI disclosures and determining whether or not an FCOI exists. They are also responsible for evaluating and monitoring FCOI management plans.

4.2 Investigators and any other research site staff who are required to disclose SFI under this policy are responsible for understanding and meeting their obligations regarding financial disclosures, as well as completing education and training if required under this under this policy, and complying with any FCOI management plan required by this policy.

5 PROCEDURE:

5.1 Disclosure of FCOI:

5.1.1 It is the responsibility of each Investigator to report any SFI known to exist in relation to each study, on the part of each researcher or research staff member taking part in the study at SHC, in the application made to the IRB for that study.

5.1.2 Researchers submit their FCOI no later than the date of submission of proposal for research on *FORM: Financial Disclosure Statement (HRP-220)*.

5.1.2.1 Researchers will update their FCOI disclosure within 30 days of discovering or acquiring a SFI as that term is defined in Section 7 of this guidance.

5.1.2.2 At a minimum, researchers will evaluate their FCOI disclosure annually, providing the IRB with any changes in the relevant FCOI information.

5.2 IRB Evaluation of FCOI:

5.2.1 IRB staff will assign two (2) IRB members to conduct the initial review of conflicts of interest identified *on FORM: Financial Disclosure Statement (HRP-220).* Disclosures will be reviewed within 60 days of their submission.

5.2.1.1 IRB committee members do not participate in the review of any conflict of interests in which the member has conflicting interest.

5.2.2 Assigned IRB members will review the reported financial interest and the research protocol and determine whether the reported financial interest could directly and significantly affect the design, conduct, or reporting of human subject research.

5.2.2.1 This review should take into account the extent to which the disclosing investigator has the ability to exercise his own discretion over or is involved in the following:

5.2.2.1.1 Subject recruitment

5.2.2.1.2 Prescreening for inclusion/exclusion criteria

5.2.2.1.3 Consent process

5.2.2.1.4 Clinical treatment/evaluation of subjects, separate from research interventions or procedures

5.2.2.1.5 Adverse event evaluation and/or reporting

5.2.2.2 If the reviewing IRB member determines that the financial interest does not create a financial conflict of interest or is otherwise being managed by investigator or study team, he or she will notify the IRB staff of this determination in writing, including the justification for coming to such a conclusion, and stop processing subsequent steps of this procedure.

5.2.3 If the reviewing IRB member determines that an FCOI exists, in addition to reporting such finding to the IRB, he or she will determine:

5.2.3.1 Whether the FCOI has the potential to adversely affect the protection of the research participants within the context of the criteria for IRB approval; or

5.2.3.2 Whether the FCOI has the potential to adversely affect the integrity of the research.

5.2.4 At any point the IRB may determine that additional review and input is necessary from the Compliance Officer and or legal department. If such further review is required, the IRB member will notify IRB staff and/or the Director of Research, who will facilitate such review and report back to the IRB at the next convened meeting.

5.2.5 If the reviewing IRB member determines that an FCOI exists, he or she will present those findings at the next convened IRB meeting so that the IRB can evaluate and discuss the FCOI and have an appropriate management plan drafted.

5.2.5.1 If the IRB decides that an FCOI can and should be managed, it will require the affected investigator to draft a written management plan. If the IRB determines that an FCOI cannot be adequately managed, then it may withhold or withdraw its approval of the study.

5.3 IRB Management of FCOI:

5.3.1 The affected investigator will draft a management plan, considering the following options:

5.3.1.1 Public disclosure of the financial interests, either in the Informed Consent Form or otherwise.

5.3.1.2 Monitoring of research by independent reviewers.

5.3.1.3 Modification of the research plan.

5.3.1.4 Disqualification from participation in all or a portion of the human research.

5.3.1.5 Divestiture of financial interests.

5.3.1.6 Severance of relationships that create the conflict of interests.

5.3.1.7 Involvement of external individuals in key portions of the protocol

5.3.1.8 Use of an external IRB

5.3.1.9 Any other effective tool or process for managing, mitigating, or eliminating the FCOI

5.3.2 The affected investigator will draft the written management plan and provide a copy to the IRB for comment and review.

5.3.3 IRB, IRB Staff, or any designated IRB subcommittee will finalize the written management plan, giving consideration to any comments made by the IRB or by the affected investigator or office.

5.3.4 IRB staff will provide the IRB and the affected investigator or office with the final written management plan, and require the affected investigator(s) to sign the plan.

5.3.5 When required, provide the final determination to the funding or regulatory agencies prior to the expenditure of any funds in relation to the study.

5.3.6 In the event that a FCOI is not identified or managed in a timely manner, a committee will be established to perform a complete retrospective review of the conflict and its effect on the research project to determine whether there was bias in the design, conduct, or reporting of such research. This review will be conducted within 120 days of the organization's determination of non-compliance.

5.4 Recordkeeping - Maintain a copy of determinations and management plans in the record for at least three (3) years.

6 MATERIALS

6.1 GUIDANCE: Institutional Conflicts of Interests (HRP-054)

6.2 FORM: Financial Disclosure Statement (HRP-220)

7 REFERENCES

7.1 Food and Drug Administration sets forth requirements for financial disclosures related to clinical trials at 21 CFR Part 54.

7.2 Public Health Service sets forth requirements for financial disclosures related to research funded under PHS grants at 42 CFR Part 50, Subpart F.

This document is available on www.sharp.com/research, IRBANA, or by contacting research@sharp.com.