FOR REFERENCE - PLEASE ALWAYS ACCESS MCN POLICY MANAGER ON THE HSHS INTRANET FOR CURRENT VERSION

FACILITY:	St. Vincent Hospital (including all St. Vincent Hospital Cancer Centers locations) St. Mary's Hospital St. Nicholas Hospital St. Clare Memorial Hospital Sacred Heart Hospital St. Joseph's Hospital	**MANUAL:** HSHS Wisconsin - Provision of Care, Treatment and Services
TITLE: Financial Conflict of Interest – Research		**ORIGINATING DEPARTMENT:** HSHS St. Vincent Hospital Cancer Research Institute
SUPERSEDES: SVGB 03/09/2020		**POLICY NUMBER:**

I. SCOPE AND APPLICABILITY:

This policy applies to HSHS St. Vincent Hospital, HSHS St. Mary's Hospital, HSHS St. Nicholas Hospital, HSHS St. Clare Memorial Hospital, HSHS Sacred Heart Hospital and HSHS St. Joseph's Hospital and its wholly-owned subsidiary and affiliated entities and corporations (hereinafter referred to as "Institution"), and all individuals (including employees, medical staff members, contractors, trustees, students, subrecipients, and others) who are involved in the design, conduct, analysis, reporting or IRB review of any Funded Research (as defined below) , protocols or proposals, humanitarian use devices (HUD), or registries, or any Research with an intent to publish, whether Funded or unfunded.

II. PURPOSE:

The purpose of this policy is to:

- promote objectivity in Research;
- provide a means for identification of Financial Conflicts of Interest (as defined below) in Research activities (as defined below);
- ensure responsible and effective oversight and management of Financial Conflict of Interests in Research in order to protect the integrity of the Research; and
- comply with regulations regarding ensuring objectivity in Public Health Service Funded Research (defined below).
- To comply with the *Ethical and Religious Directives for Catholic Health Care Services* (ERDs) which state: #4 A Catholic health care institution, especially a teaching hospital, will promote medical research consistent with its mission of providing health care and with concern for the responsible stewardship of health care resources. Such medical research must adhere to Catholic moral principles. #31 No one should be the subject of medical or genetic experimentation, even if it is therapeutic, unless the person or surrogate first has given free and informed consent. In instances of nontherapeutic experimentation, the surrogate can give this consent only if the experiment entails no significant risk to the person's well-being. Moreover, the greater the person's incompetency and vulnerability, the greater the reasons must be to perform any medical experimentation, especially nontherapeutic.

III. DEFINITIONS:

1. Family members – includes spouse and dependent children.

2. Financial Conflict of Interest (FCOI) means a Significant Financial Interest that could directly and significantly affect or result in bias in the design, conduct or reporting of Research.

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

4. Funded - means any type of external financial support for Research whether through grant, contract, or cooperative agreement.

5. Institution – means HSHS St. Vincent Hospital, HSHS St. Mary's Hospital, HSHS St. Nicholas Hospital, HSHS St. Clare Memorial Hospital, HSHS Sacred Heart Hospital or HSHS St. Joseph's Hospital and its affiliates, subsidiaries, and operating units.

6. Institutional Official – the Institutional Official is the individual who is authorized to act on behalf of the Institution with respect to Research activities, and who is charged with ensuring that human subjects research is conducted in accordance with all applicable legal and ethical requirements.

7. Institutional Responsibilities - a Respondent's professional responsibilities on behalf of the Institution, including activities such as Research, teaching, clinical or other professional practice, committee memberships, and service on panels such as the Institutional Review Board (IRB).

8. Institutional Review Board (IRB) – a committee that reviews Research and Research proposals to help ensure that a patient's rights and welfare as a Research subject are protected and that the study is carried out in an ethical manner.

9. Institution of Higher Education – an educational institution as described at 20 U.S.C. § 1001(a), that admits students who have graduated from a school of secondary education or received a certificate of equivalence, that provides education leading toward a bachelors or higher degree and meets accreditation or other similar requirements.

10. Project Director/Principal Investigator (PD/PI) – The individual(s) designated to have the appropriate level of authority and responsibility to direct the Research project or program. The PD/PI is included in the definitions of Researcher and Senior/Key Personnel (as defined below).

11. Public Health Service (PHS) of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

12. Public Health Service (PHS) Awarding Component – means the organizational unit of the Public Health Service that funds or supports the Research.

13. Public Health Service (PHS) Financial Conflict of Interest (FCOI) Regulations – the regulations required of entities engaged in Research, cooperative agreements, grants, and other activities that are Funded or otherwise supported by the Public Health Service, as set forth at 42 C.F.R. Part 50 and 45 C.F.R. Part 94, including sub-grantees and sub-recipients.

14. Research – means a systematic investigation that is designed to contribute to generalizable scientific or medical knowledge or knowledge relating to health, medicine or public health, including basic and applied research, development, testing, and evaluation of investigational products or therapies, or any process undertaken to evaluate the safety and/or efficacy of a drug, medical device, or other therapeutic agent (including retrospective data collections or reviews), or behavioral and social sciences research. Research may also include activities which are Funded directly or indirectly by grants or awards from the U.S. Public Health Service, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training award, program project, or research resources award.

15. Research Conflicts of Interest Committee ("Committee") – individuals identified pursuant to this policy to review all disclosures of Significant Financial Interests (SFI), determine if a SFI creates a Financial Conflict of Interest (FCOI), and assist in the identification and selection of measures to manage the FCOI.

16. Researcher – includes any principal investigator, project director, co-investigator(s), sub-investigator(s), and any other Senior/Key Personnel, including anyone, regardless of title or position, who has responsibility for the design, conduct, analysis, or reporting of the Research. A collaborator or consultant may be a Researcher under this policy.

17. Respondent – institution's physicians, researchers, IRB members, or any other research support staff

18. Reviewing Official – for purposes of this policy, the Reviewing Official is the individual required to review

disclosures of Financial Interests and to ensure compliance with this policy and any FCOI Management Plans. The Director of Research shall constitute the designated Reviewing Official under this policy and the PHS FCOI regulations.

19. Senior/Key Personnel – means the PD/PI and any other individuals identified as Senior/Key personnel by the Institution in a grant application, progress report, or any other report submitted to the PHS by the Institution under 42 CFR Part 50 Subpart F.

20. Significant Financial Interest – a Financial Interest of a Respondent (or his or her spouse or dependent children), that reasonably appears to be related to the Respondent's Institutional Responsibilities and includes one or more of the following:

    A. With regard to **publicly traded entities**:
    - Any remuneration received from the entity in the twelve months preceding the disclosure PLUS the value of any equity interest in the entity (when aggregated) exceeds $5,000.
        - Remuneration includes income, salary or other compensation, including consulting fees, honoraria, gifts, paid authorship, or bonus payments/stipends.
        - Equity interest includes any stock, stock option, or other ownership interest.

    B. With regard to **non-publicly traded entities**:
    - Any remuneration received from the entity in the twelve months preceding the disclosure exceeding $5,000.
    - ANY equity interest (e.g., stock, stock options, or other ownership interest) held by the Respondent (or their spouse or dependent children)

    C. Intellectual property rights and interests, such as patents and copyrights, for which income (such as, but not limited to, royalties) is received.

    D. ANY reimbursed or sponsored travel and related expenses related to a Respondent's Institutional Responsibilities, unless the reimbursement or sponsorship is from a government agency, or an academic medical center, a teaching hospital, or a research institute that is affiliated with an Institution of Higher Education.

    E. Significant Financial Interest does not include the following:
    - So long as Respondent is an employee of the Institution:
        - Salary, royalties or other remuneration paid by the Institution to the Respondent as an employee;
        - Intellectual property rights and royalties shared with Institution as an employee;
        - An ownership interest in Institution, if Institution is for-profit.
    - Income from investment vehicles such as mutual funds and retirement accounts, so long as Respondent does not directly control investment decisions of those funds;
    - Income from seminars, lectures, teaching engagements or service on advisory committees or review panels sponsored by a government agency, Institution of Higher Education or an affiliated research institute, or an academic medical center or teaching hospital.

    F. Service as an officer, director, or in any other fiduciary role for a financially interested company; and

    G. Other Financial Interests as may be determined by the Committee.

IV. POLICY:

1. The Institution evaluates Financial Interests involving Research investigators and any other personnel involved in the design, conduct, analysis, reporting or IRB review of Research.

2. Institution's physicians, Researchers, Institutional Review Board ("IRB") members, or any other Research support staff ("Respondents") shall be trained on and comply with this policy and all applicable legal and regulatory requirements related to Financial Conflicts of Interest in Research.

3. Respondents shall disclose all Significant Financial Interests under this policy, or under any law or regulation, or that might raise questions as to the objectivity of Research conducted or overseen by the Respondent.

4. Disclosure of Significant Financial Interests will be made to the Reviewing Official. Respondent shall cooperate with and comply with the Reviewing Official and the Committee in their evaluation. If a Significant Financial

Interest is determined to create a Financial Conflict of Interest (FCOI), the respondent shall also cooperate with and comply with oversight and management of such FCOI as directed by the Reviewing Official and/or the IRB of record.

5. Respondents must disclose any Significant Financial Interests of the Respondent and of the Respondent's spouse and/or dependent children.

6. This policy will be made publicly available on the Institution's public website.

7. For any research Funded by the Public Health Service (PHS), current Financial Conflicts of Interest of Senior/Key personnel will be disclosed in writing to any requestor within 5 business days.

V. POLICY REQUIREMENTS:

1. Training on Conflicts of Interest. Prior to engaging in any Funded Research, each Respondent must complete the Institution's training program with regard to this policy, their obligations regarding disclosures, and the PHS FCOI regulations. Training must be repeated at least every four (4) years thereafter, and within thirty (30) days of when any of the following occurs:
   A. When this Policy, the Disclosure Form, or Institution procedures related to this Policy are revised in any manner that affects the Respondent's responsibilities thereto;

   B. A Respondent is newly hired, is appointed by, or receives approval of medical staff privileges from, the Institution; or

   C. A Respondent is found to not be in compliance with this Policy or a management plan applicable to that Respondent.

2. Disclosures of Financial Interest

   A. In addition to any forms required by the FDA or the sponsor of a research study, each Respondent must disclose any Financial Interests to the Reviewing Official in accordance with this policy and applicable laws and regulations.

   B. Prior to the expenditure of any funds for PHS Funded Research, the Reviewing Official will review all affected Respondent's Disclosure Forms; determine whether any Significant Financial Interests relate to the PHS-supported Research; determine whether a FCOI exists; and, if so, develop and implement a management plan that specifies the actions that have been, and will be taken to manage such FCOI. If the Research is PHS-Funded, the Institution shall provide to the PHS Awarding Component an FCOI report regarding any Respondent's SFI found to be an FCOI along with the implemented management plan.

   C. To disclose Financial Interests or certify the absence of any such Financial Interests, Respondents must complete the Institution's Research Financial Conflict of Interest Questionnaire. If the Respondent reports any Financial Interests, the Respondent must also provide details regarding Financial Interests.

   D. Disclosures regarding reimbursed or sponsored travel must include:
      i. A summary of the purpose of the trip;
      ii. An identification of the sponsor of the trip;
      iii. The destination of the trip;
      iv. The duration of the trip;
      v. Any additional information requested by the Reviewing Official to assist in determining whether the travel constitutes a financial conflict of interest.

   E. Respondents must complete the Institution's Research Financial Conflict of Interest Questionnaire for review by the Reviewing Official prior to participating in an IRB review of a study, prior to engagement in a Funded study, prior to the submission date of a proposal for PHS-Funded research, on an annual basis, and upon any relevant change in financial circumstances of a Respondent. If a Respondent discovers or acquires (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest, the Respondent shall report the change to the Reviewing Official within 30 days of the Respondent becoming aware of the change.

   F. Respondents shall disclose Financial Conflicts of Interest to the sponsors of any program or editors of any publication to which Respondent submits a manuscript concerning the Research or any substantive written

or oral public communication of the results of the Research, in accordance with the requirements of such program sponsor or publication.

3. Research Conflict of Interest Committee

   A. Members of the Committee shall include the Director of Research, as the Reviewing Official, the HSHS Wisconsin Division Director of Compliance and HSHS Wisconsin Division Vice President of Legal Affairs. Additional members may be included who are experienced in the oversight of Financial Conflicts of Interest, or applicable laws and regulations.

   B. The Committee will meet as necessary to conduct the business contemplated by this Policy.

   C. The Committee may convene via e-mail communications, teleconference, or in person, as necessary and appropriate. No less than annually, members of the Committee shall convene to review compliance with current management plans of conflicts identified throughout the prior year, and to evaluate new disclosures of Significant Financial Interests to determine if they create a Financial Conflict of Interest. Documentation of Committee meetings will be maintained.

4. Research Conflict of Interest Committee Review

   A. Disclosures of any Significant Financial Interest shall be presented to and reviewed by the Committee, along with any additional information that may be relevant to the deliberations of the Committee. The Committee may request the Respondent for any additional information necessary to aid in its review.

   B. The Committee shall determine whether a Significant Financial Interest may adversely affect the rights or welfare of research subjects and/or integrity of the data or result in bias or the appearance of bias in the design, conduct, analysis or reporting of the Research. To determine whether a Significant Financial Interest creates a Financial Conflict of Interest, the Committee will consider the following two step process:

      i. Determine whether the Respondent's SFI is related to Funded Research. A Respondent's SFI is related to Funded research when the Committee determines that the SFI:
         1. Could be affected by the Funded research, or
         2. Is in an entity whose Financial Interest could be affected by the Funded research.

      ii. Determine whether the SFI can **directly and significantly** affect the design, conduct, or reporting of the Funded research by considering, at a minimum, the following:
         1. What specific involvement does the Respondent have in the design, conduct, or reporting of research?
         2. What is the size of the study or target enrollment?
         3. How many investigators and/or sites are involved in the study?
         4. What percentage of study enrollments could be influenced by the Respondent?
         5. Does the Respondent have any involvement in the study analysis?
         6. Are other study personnel are also involved in the study's design, conduct, analysis or reporting?
         7. Other inherent controls in the design of the study such as blinding to the Researcher or data analysis conducted an independent party.

   C. The Committee will determine whether a Financial Conflict of Interest exists and will document their decision using the Research Financial Conflict of Interest Committee Decision Form.

   D. If the Committee determines that the FCOI is too significant to manage the Committee may prohibit the Respondent from conducting the Research.

   E. Alternatively, the Committee may recommend any reasonable management plan including, but not limited to, the following options to protect the rights or welfare of research subjects and/or integrity of the data, or prevent bias or the appearance of bias in the design, conduct, analysis or reporting of the Research:

      i. Disclosure of Financial Conflict of Interest directly to participants via the research informed consent form.
      ii. Appointment of a monitor (i.e., an appropriately qualified individual not directly involved with the

research in question) capable of taking measures to protect the design, conduct, and report of the research against bias resulting from the Respondent's conflict of interest.

iii. Change of Respondent responsibilities, or restriction of Respondent from participation in all or a portion of the research (e.g., informed consent process).
iv. Appointment of a co-investigator.
v. Limitation on number of subject enrollments allowed by the Respondent
vi. Reduction or elimination of the Financial Interest (e.g., sale of an equity interest)
vii. Severance of relationships that create financial conflicts
viii. For IRB members, abstaining from associated IRB initial or continuing review except to provide information as requested by the IRB.
ix. Other activities reasonably calculated to protect the rights or welfare of research subjects and/or integrity of the data or prevent bias or the appearance of bias in the design, conduct, analysis or reporting of the Research.

F. The Committee shall inform the Respondent (and IRB of record if necessary) of the management plan. The IRB may require additional safeguards or demand reduction or elimination of the Financial Conflict of Interest. The Respondent must acknowledge and accept the Committee's recommendation by signing off on the management plan.

G. The Committee shall develop a process for monitoring compliance with each management plan that is approved until the Research project is completed, including requirements for oversight and submission of reports regarding compliance with the management plan. The IRB of record may provide additional input into the plan. The Committee may send monitors to observe conduct of Research activities, review study documentation, or take any other action the Committee deems appropriate to ensure objectivity in Research activities.

H. The Committee may suspend its approval of the conduct of the Research by the Respondent if the Respondent fails to comply with the management plan. The Reviewing Official shall advise the IRB of record of the failure, and the IRB shall consider whether such failure adversely impacts the protection of human subjects. If the Research project is PHS-supported, the Reviewing Official shall notify the PHS Awarding Component of the Respondent's failure to comply with the management plan in accordance with the provisions of this Policy, below.

5. Ongoing Research.

A. Ongoing Research, including ongoing Funded Research, may be reviewed for FCOI, and additional disclosures may be required when:

i. A Respondent who is newly participating in the Research project discloses a Significant Financial Interest;
ii. An existing Respondent discloses a new Significant Financial Interest;
iii. There is a reasonable belief that a Significant Financial Interest was not disclosed by a Respondent or, for whatever reason, was not previously reviewed by the Institution; or
iv. Other reasonable cause exists to review ongoing Funded Research for FCOI.

B. The Reviewing Official will notify affected Respondent(s) and the Committee of the new disclosure related to ongoing Research. The Reviewing Official will request any additional information necessary from the Respondent. The Respondent(s) will provide the necessary disclosures within twenty (20) days of receiving the request. Depending on the nature of the possible Significant Financial Interest, the Reviewing Official may determine that additional interim measures are necessary with regard to the Respondent's participation in the Research between the date disclosure is requested and the completion of the Committee review, and may mandate the implementation of such measures in the Reviewing Official's discretion.

C. The Reviewing Official will, within thirty (30) days of receiving the requested disclosure(s):

i. Convene a meeting of the Committee to review the disclosure(s) of Significant Financial Interest(s);
ii. Determine whether the Significant Financial Interest(s) are related to Funded Research;
iii. Determine whether a FCOI exists; and,
iv. If a FCOI exists, implement, on at least an interim basis, a management plan for such FCOI.

D. The Committee's review and decision will be completed and documented within sixty (60) days of the new disclosure, any new management plan or revision to an existing management plan will be implemented.

6. Retrospective Review; Non-Compliance – PHS-funded Research.

   A. If a Respondent fails to disclose a Significant Financial Interest that is determined to be a FCOI or fails to comply with a FCOI management plan; or if Institution fails to review or manage a FCOI, a retrospective review of the Respondent's activities shall be conducted by the Committee or its designees within 120 days of determining non-compliance. The focus of the review will be to determine whether any affected PHS-Funded Research shows bias in design, conduct or reporting. Depending on the nature of the FCOI, the Institution, through the Reviewing Official, may implement additional interim measures with regard to the Respondent's participation in PHS-Funded Research during the period of time that the retrospective review is being conducted.

   B. Documentation of the retrospective review must include at least the following information:
      i. Project number;
      ii. Project title;
      iii. PD/PI name (if multiple PD/PI, contact PD/PI name);
      iv. Respondent with FCOI;
      v. Entity with which Respondent had FCOI;
      vi. Reasons for retrospective review;
      vii. Detailed description of methodology used in retrospective review, including composition of review panel and documents reviewed;
      viii. Findings of the review panel;
      ix. Conclusions of review.

   C. If appropriate, the previously submitted FCOI report to the PHS awarding component shall be updated based on the findings of the Committee. As appropriate, a FCOI management plan shall be implemented or revised.

   D. If, through the retrospective review, bias is found and the Research is PHS-supported Research, the Reviewing Official and the Institutional Official shall notify the PHS Awarding Component and submit a mitigation report, which shall include:
      i. the documentation prepared in the retrospective review,
      ii. a description of the impact of the bias on the Research, and
      iii. the plan of action or actions taken to eliminate or mitigate the impact of the bias (including an assessment of whether any actual harm has or may occur and an analysis of whether the Research data is reliable or can be salvaged).
      iv. Thereafter, the Institution will submit FCOI reports annually as outlined in number 7 below.

7. Reporting of Conflicts of Interest – PHS-funded Research.

   A. Prior to expenditure of any PHS funds for a Research project, the Institution shall provide the PHS Awarding Component a FCOI report detailing:
      i. Any Significant Financial Interest which the Institution has determined constitutes a FCOI; and
      ii. A description of the management plan. If the FCOI has been eliminated, no report is required.

   B. If a FCOI is identified in an ongoing PHS-Funded Research project, within sixty (60) days Institution shall advise the PHS Awarding Component of the FCOI and the management plan. If the FCOI was not timely disclosed or managed, a retrospective review under Section 6 of this policy, including determination of possible bias, is required and, if applicable, a mitigation report as outlined in 6.D.

   C. Reports of FCOI to the PHS Awarding Agency must include sufficient information to permit the agency to understand the nature and extent of the conflict, and to evaluate the management plan. At a minimum, the report must include:
      i. Project number;
      ii. PD/PI or Contact PD/PI;
      iii. Name of Respondent with FCOI;
      iv. Name of entity with which the Respondent has a FCOI;
      v. Nature of the Financial Interest (equity, compensation, etc.);
      vi. Value of the Financial Interest (may be dollar ranges, or statement that value cannot readily be determined by reference to publicly available prices or fair market value measures);
      vii. A description of how the Financial Interest relates to the PHS-supported Research and the basis for the determination that the interests constitutes a FCOI with such Research;

viii. A description of the key elements of the management plan, including:
1. Role and principal duties of the Respondent with the FCOI in the Research;
2. Conditions of the management plan;
3. How the management plan is designed to safeguard objectivity in research;
4. Confirmation of the Respondent's agreement to the management plan;
5. How the management plan will be monitored to ensure Respondent compliance;
6. Other information as needed.

D. Previously reported FCOI(s) shall be updated annually, advising the Awarding Component of the status of the FCOI, any changes to the management plan, or an explanation of why the FCOI no longer exists. Updates will be provided for the duration of the project period, including extensions, whether or not funded.

8. Enforcement Mechanisms/Remedies:

A. If a Respondent fails to report a relevant Significant Financial Interest, the Committee may create an oversight plan to deal with post-hoc, incidental, or untimely disclosures.

B. If a Respondent fails to comply with the oversight or management plan established by the Committee, the right to conduct research at Institution or an Institution component may be suspended or revoked.

C. In any case where the Department of Health and Human Services determines that a PHS-Funded research project intended to evaluate the safety or effectiveness of a drug, medical device, or treatment involved a Respondent with an FCOI, or an FCOI that was not managed or reported by the Institution, the Respondent shall be required to disclose the FCOI in each public presentation of the results of the research. In addition, the Institution may require updates/addendum(-a) to previously published presentations for any disclosures not properly reported prior to submission.

9. Cooperation with PHS Component Agencies. PHS agencies have broad authority with respect to corrective actions to maintain objectivity in research. Institution will cooperate with PHS agencies, and will provide access to all records pertinent to compliance with the PHS FCOI regulations. The primary individuals interacting with PHS agencies under this policy will be the Institutional Official and the Reviewing Official, or their designees.

10. Public Availability of Information Regarding FCOI – PHS Funded Research

A. Prior to the expenditure of any funds under a PHS-Funded Research project, Institution will make publicly available by written response to any requestor within 5 business days of receipt of a request, information regarding any SFI disclosed that:
i. Is still held by Senior/Key personnel;
ii. Is related to the PHS-supported Research;
iii. Is determined to constitute a FCOI.

B. Information made available by written response will include, at a minimum:
i. The Respondent's name;
ii. The Respondent's title and role in the Research project;
iii. The name of the entity in which the SFI exists;
iv. The nature of the SFI;
v. The approximate dollar value of the SFI, which can be set forth in ranges:
vi. 1. $0-$4,999
2. $5,000-$9,999
3. $10,000-$19,999
4. $20,000-$100,000 in increments of $20,000
5. > $100,000 in increments of $50,000
6. A statement that the value of the interest cannot be readily determined through reference to public prices or other measures of fair market value.

C. The written responses regarding FCOI, must note that the information is subject to updates pursuant to the PHS FCOI regulations.

D. Information regarding the FCOI made publicly available under this section of this Policy must be retained for at least three (3) years from the date last updated.

11. Sponsor Certification. Sponsors of Research (e.g., pharmaceutical sponsors conducting research under an investigational new drug (IND) application) must disclose Financial Interests and arrangements for any Respondents conducting Research, the data from which may be submitted to the FDA for review. Researchers must comply with all Sponsor requirements.

    A. Form FDA 3454 (or other document designated by FDA) is used to certify that all Respondents involved in the conduct of the Research do not have Financial Interests, in accordance with FDA requirements.

    B. Form FDA 3455 (or other document designated by FDA) is used to disclose any Financial Interests of Respondents involved in the conduct of the Research and steps taken to assure data is not biased.

    C. Sponsors of Research are responsible for complying with any other applicable disclosure or reporting requirements.

12. Maintenance of Records. Records shall be maintained for at least three (3) years from the date the final expenditures report is submitted to PHS or kept pursuant to 45 CFR 74.53(b) or 92.42(b) where applicable. This applies to records relating to all Respondent disclosures of Financial Interests and the Institution's review of, and response to, such disclosures whether or not the disclosure resulted in the Institution's determination of an FCOI, as well as actions taken.
13. Subrecipient FCOI Management – PHS-funded Research. Pursuant to its responsibilities found in 42 CFR 50 regarding the management of FCOI of Institution's subrecipients, the following requirements are in place for PHS-Funded research:

    A. Institution shall incorporate requirements that subrecipient(s), affiliates, and any contracted services for the PHS-Funded research (if any) comply with this policy and requirements set forth by the Research Conflicts of Interest Committee and/or the IRB.
        i. Each applicable funding instrument shall establish whether the subrecipient will follow the Institution's or subrecipient's FCOI policy.
        ii. If subrecipient will be following its own policy, the Institution will require the subrecipient to furnish a copy of the relevant policy and certification that its policy is in compliance with the federal regulations.
        iii. Institution shall include in its written agreement with subrecipient a requirement to report FCOIs for its Investigators in a time frame that allows the Institution to report identified FCOIs to the NIH as required by the regulation (e.g., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI).
        iv. The Institution may, with reasonable notice, solicit and review subrecipient Investigator disclosures, that enable Institution to identify, manage, and report identified FCOIs to the NIH.

REFERENCES:

1. 45 CFR 46.107
2. Declaration of Helsinki
3. 42 CFR Part 50 and 45 CFR Part 94; Final Rule. *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors*. Federal Register. August 25, 2011, Vol. 76, No.165, pp. 53256-53293.
4. National Institutes of Health. *NIH Grants Policy Statement*: *Financial conflict of interest, responsibility of applicants for promoting objectivity in research, free from bias, FCOI, FCOIs, FCOI report, 42 CFR 5. Revised December, 2019. Ethical and Religious Directives for Catholic Health Care Services, Sixth Edition*
5. 21 CFR 56.107 (e)
6. 21 CFR 54.2 (a) (b) (f)
7. 21 CFR 312.53
8. 21 CFR 812.43