Saint Mary's College of California
Policy on Disclosure of Financial Interests and Management of Conflicts of Interest for Public Health Service and PHS-compliant Sponsor Research Awards

Responsible Officer:	Senior Vice President for Academic Affairs and Provost
Responsible Office:	Academic Affairs
Issuance Date:	October 31, 2022
Effective Date:	February 20, 2026
Last Review Date:	February 20, 2026
Scope:	This policy for disclosure and management of conflicts of interest applies to all grants and cooperative agreements (other than Phase I SBIR and STTR applications) with an issue date of the Notice of Award on or after August 24, 2012, and to solicitations issued and contracts awarded after August 24, 2012 that are submitted to Public Health Service (PHS) agencies and other sponsors that adopt the PHS policy for research.

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I. POLICY SUMMARY

Purpose

Saint Mary's College of California (hereafter referred to as "Saint Mary's" or "the College") establishes this Policy for implementation of requirements related to financial disclosures by Investigators who are involved with submitting proposals to Public Health Service (PHS) agencies and other PHS-compliant sponsors that adopt the PHS policy for research.

It is the policy of Saint Mary's College of California to ensure that research is not biased in its design, conduct, or reporting, and to ensure especially the protection of human subjects, by requiring disclosure and review of certain outside activities, and where appropriate, by managing and reporting significant financial interests that might present a real or perceived conflict of interest with an individual's institutional responsibilities in such a manner as to appear to directly and significantly compromise the integrity of research.

This policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements, and research funded by other PHS-compliant sponsors, will be free from bias resulting from Investigator financial conflicts of interest.

Scope

The federal Department of Health and Human Services (HHS) has determined, pursuant to 42 CFR Part 50, Subpart F and 45 CFR Part 94, as revised on August 25, 2011, that effective no later

than August 24, 2012, Public Health Service (PHS)-sponsored Investigators shall be subject to specific requirements regarding the disclosure and management of conflicts of interest with regard to research in order to provide a reasonable expectation that PHS-sponsored research will be conducted free of bias resulting from Investigator Financial Conflicts of Interest.

These regulations require Saint Mary's College of California (hereafter referred to as "Saint Mary's" or "the College") to maintain a written policy on conflict of interest disclosure as a condition for receiving PHS awards. Therefore, the College is obligated to establish this Policy consistent with these regulations to require disclosure, and identification and management of Financial Conflicts of Interest for all Investigators supported by PHS (NIH, CDC, FDA, etc.) research awards and other sponsors that adopt the PHS policy (for example, American Heart Association and the American Cancer Society). This policy is also used to implement the federal Department of Energy (DOE) Interim Conflict of Interest Policy for Financial Assistance, which applies to all DOE financial assistance applications and awards with the exception of those from the Office of Indian Energy and Phase I SBIR/STTR applications and financial assistance awards.

Application

This policy applies to all grants and cooperative agreements with an issue date of the Notice of Award on or after August 24, 2012 (including noncompeting continuations), and to solicitations issued and contracts awarded after August 24, 2012 that are for research. These federal requirements are applicable to all proposals for extramural awards submitted to PHS.

The policy also applies to subgrantees, contractors, or collaborators of Saint Mary's College who receive and / or seek support from PHS or other PHS-compliant sponsors, unless those individuals can provide written assurance to a Designated Official that they are subject to a similar financial conflict of interest policy.

Consistent with PHS regulations, this Policy will be made available via a publicly-accessible website. All Saint Mary's College Investigators, as defined in Section II, who are responsible for the design, conduct, or reporting of PHS-supported research, and Investigators seeking PHS research support, shall be informed where this Policy and relevant reporting requirements may be accessed via the web.

II. DEFINITIONS[1]

Conflict of Interest Committee (COI Committee).[2] A Committee which may be appointed at the initiation of the Provost (or designee) to review Investigators' Significant Financial Interests related to research funded by the PHS or other PHS-compliant sponsors, and to serve as the Designated Official(s) who determines whether any of the Significant Financial Interests constitutes a Financial Conflict of Interest.

[1] Most definitions are derived from Public Health Service regulations 42 CFR Part 50, Subpart F, Promoting Objectivity in Research. Accessed September 20, 2022 at https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F.

[2] The procedure for the constitution of the COI Committee is derived from the Saint Mary's College Faculty Handbook, section 1.7.3.1 Accessed February 8, 2026 at https://www.stmarys-ca.edu/faculty-handbook.

When constituted, the COI Committee consists of five members selected at the initiation of the Provost for the purpose of hearing Conflict of Interest Case(s) following the procedure for a jury selection process to form a committee as outlined in Saint Mary's Faculty Handbook (FHB) 1.7.3.1.

1) Membership eligibility: All tenured members of the faculty are eligible for selection to a COI Committee, with exceptions as noted in FHB 1.7.3.1.

2) Creation of a pool: The Faculty Governance Coordinator will create the pool of faculty members who are eligible for service on a COI Committee following the process outlined in FHB 1.7.3.1.

3) COI Committee Creation: The committee will be created as follows:
   - Each Investigator who is subject to COI Committee review will be informed of the current pool of twelve faculty members.
   - Each Investigator who is subject to COI Committee review may challenge two members within ten (10) school days of the actual notice of the composition of the COI Committee. Challenges are peremptory and without personal or professional prejudice.
   - The Committee is reduced to five by lot by the chair of the Academic Senate.
   - The chair of the Academic Senate will ensure that the final Committee of five members be operative within five (5) school days from its creation.

4) Committee Chair: The COI Committee will determine its own chair.

Designated Official(s). An official or officials designated by the Provost, or designee, to solicit and review Investigators' completed Disclosure of Financial Interest forms and who may determine whether the Investigator has a Financial Conflict of Interest.

Disclosure of significant financial interests. An Investigator's disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI). A significant financial interest that could directly and significantly affect the design, conduct, or reporting of research funded by PHS or other PHS-compliant sponsor.

HHS. The United States Department of Health and Human Services.

Institution. Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, research funding from PHS or other PHS-compliant sponsor.

Institutional responsibilities. An Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution, which may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or other boards.

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 funded by or proposed to the PHS or other PHS-compliant sponsor, which may include, for example, collaborators or consultants.

Manage. Taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PHS. The Public Health Service 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).

PHS-compliant sponsor. A sponsor that has adopted the PHS policy for research.

Principal Investigator / Project Director (PI/PD). An Investigator who has primary responsibility for the scientific and technical conduct, reporting, fiscal, and programmatic administration of a sponsored project. The PI/PD is included in the definitions of senior/key personnel and Investigator under this Policy.

Research. 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 this Policy, the term includes any such activity for which research funding is available from a PHS-awarding agency or other PHS-compliant sponsor 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.

Senior / Key Personnel. means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted by the Institution to the PHS or other PHS-compliant sponsor.

Significant financial interest (SFI). Consistent with federal regulations (42 CFR Part 50.603 and 45 CFR Part 94.3), a Significant Financial Interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse or registered domestic partner[3] and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

A. With regard to any publicly traded entity, an **SFI** exists if the value of any remuneration (other than remuneration described in the exceptions below) 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. Included are salary (other than salary described in the exceptions below), consulting fees, honoraria, paid

[3] The inclusion of "registered domestic partner" is consistent with California State law, Family Code section 297 et seq., but is not specifically required under PHS regulations. California State Law, accessed October 9, 2022, at https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=297.&lawCode=FAM.

authorship, and the equity interest value at the date of disclosure as determined by public prices or other reasonable measure of fair market value;

B. With regard to any non-publicly traded entity, including a non-U.S. institution of higher education or a non-U.S. government agency, an **SFI** exists if the value of any remuneration (other than remuneration described in the exceptions below) 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, registered domestic partner, or dependent children) holds any equity interest;

C. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income, exceeding $5,000 during the twelve months preceding disclosure from such rights and interests. However, SFIs do not include royalties received from Saint Mary's College of California;

D. 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 the Investigator's Institutional Responsibilities must also be disclosed when the travel is reimbursed or sponsored by an individual or entity other than a U.S. federal, state or local government agency, a U.S. institution of higher education, or a research institute, academic medical center, or hospital affiliated with a U.S. institution of higher education.

Exceptions: The term **Significant Financial Interest** does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by Saint Mary's to an Investigator who is currently employed or otherwise appointed by the College;
- Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a government agency of the United States (including federal, state, or local government), a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with a U.S. institution of higher education;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control investment decisions.

III. POLICY TEXT

A. Disclosure of Significant Financial Interests

Investigators seeking research funding or receiving research support from a PHS agency or other PHS-compliant sponsor are required to disclose Significant Financial Interests related to their Institutional Responsibilities. These Investigators shall submit a disclosure of Significant Financial Interests in accordance with campus implementation procedures.

The requirement that an Investigator disclose a Significant Financial Interest under the terms of this Policy does not in and of itself imply the existence of an actual or potential

financial conflict of interest. The existence of a Financial Conflict of Interest, based upon the relationship of the Investigators' Significant Financial Interests to the Investigators' Institutional Responsibilities, is determined by a Designated Official or the COI Committee with input from the Investigator. If a Financial Conflict of Interest is identified, the Designated Official(s) or the COI Committee shall recommend additional steps to manage or eliminate the conflict to the Provost or designee who is authorized to act on that recommendation.

Investigators as defined by this Policy, shall disclose to the College all Significant Financial Interests related to their Institutional Responsibilities, no later than at the time of application for funding from PHS or other PHS-compliant sponsor.

This initial disclosure responsibility is separate from and in addition to an Investigator's ongoing duty throughout the period of a research award from PHS or other PHS-compliant sponsor to disclose to the Designated Official the Investigator's Significant Financial Interests, and those of the Investigator's spouse or registered domestic partner and dependent children, related to the Investigator's Institutional Responsibilities:

- Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage or inheritance) any new Significant Financial Interest (with the exception of travel disclosures, noted below); and
- At least annually throughout the period of the award.

Before joining an ongoing research project funded by PHS or other PHS-compliant sponsor, new Investigators must submit a disclosure of Significant Financial Interests to the campus.

Under the terms of this Policy, Principal Investigators must identify all Investigators on the award (that is, all individuals who will have responsibility for designing, conducting, or reporting the research to be funded by PHS or other PHS-compliant sponsor) who are required to disclose Significant Financial Interests.

Sponsored or reimbursed travel may be disclosed:

a) Prospectively listing all anticipated travel (including information about the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip, as well as any other information that may be required by the College) for the twelve (12) month period following the filing of the Investigator's annual disclosure form; and/or
b) Within thirty (30) days of the occurrence of travel that either was not listed on the prospective annual travel report pursuant to paragraph a) or that significantly varied in the threshold reporting details from what was listed in the prospective report.

Collaborators from other institutions who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a sub-grant or subcontract from the College are expected to comply with the policies and procedures for disclosure and review of a Significant Financial Interests at the institution at which they are employed or, if their institution does not have a conflict of interest policy that complies with Department of Health and Human Services (HHS) regulations, they must comply with the

College's policies and procedures for disclosure and review of Significant Financial Interests related to awards sponsored by PHS or other PHS-compliant sponsor.

Subawards issued by the College will ask the subrecipient institution to certify that its policy is in compliance with DHHS conflict of interest regulations, and unless the subrecipient does not have a DHHS-compliant policy, will indicate that the recipient organization is responsible for reviewing the disclosures submitted by its Investigators and, if a Financial Conflict of Interest is identified, for sending the College notification of the conflict and of the subrecipient institution's plan to manage, reduce, or eliminate the identified conflicts, in accordance with PHS reporting requirements.

Collaborators who share responsibility for the design, conduct, and reporting of research results and who will participate in research under an independent consulting agreement issued by the College should be identified as Investigators by the PI and should complete the College disclosure forms. If, upon review, the College determines that these financial interests could directly and significantly affect the design, conduct, or reporting of the research to be performed under the agreement, consultants will be expected to adhere to the plans put in place to eliminate, reduce or manage the identified conflicts of interest.

B. Review of Disclosures; Management Plan

With each proposal, progress report, incremental funding or extension made to PHS or other PHS-compliant sponsor, Investigators' Significant Financial Interests disclosures will be reviewed by the Designated Official(s) to determine whether there are any Significant Financial Interests that reasonably appear to be related to the research activity funded by PHS or other PHS-compliant sponsor in which the Investigator is engaged. Investigators shall have an opportunity to indicate whether or not they believe the Significant Financial Interest(s) they reported are related to such research activities.

In the event that Designated Official(s) conclude that an Investigator's Significant Financial Interest reasonably appears to directly and significantly affect the design, conduct or reporting of research funded by PHS or other PHS-compliant sponsor, the Designated Official shall appoint a COI Committee to conduct a review of the case. When it is determined that there is a Financial Conflict of Interest, the COI Committee shall make a final recommendation to the Designated Official about whether any conditions or restrictions should be placed on the project to eliminate or manage the Financial Conflict of Interest before support from PHS or other PHS-compliant sponsor can be accepted.

The management plan is to be implemented prior to the College's expenditure of funds awarded for the research project by PHS or other PHS-compliant sponsor, and shall specify the actions that are required to manage the Financial Conflict of Interest, and shall include:

- The role and principal duties of the conflicted Investigator;
- Conditions of the management plan;
- How the plan will safeguard objectivity in the research activity;
- Confirmation of the Investigator's agreement to the plan; and
- How the plan will be monitored.

The same review process takes place when an Investigator reports a new Significant Financial Interest.

C. Reporting to PHS or PHS-compliant sponsor

Prior to the College's expenditure of any funds provided under a PHS or other PHS-compliant sponsor award, the College must provide to the sponsor an initial report regarding Investigator Financial Conflict of Interest. If Financial Conflicts of Interest are eliminated before research funds are expended, the College is not required to submit a report to the sponsor.

During the period of the award, the College shall, within 60 days of receipt of disclosure of a new or newly-discovered Significant Financial Interest, review the disclosure, determine whether it is related to research funded by PHS or other PHS-compliant sponsor, determine whether it constitutes a Financial Conflict of Interest, and if so, implement a management plan and report the Financial Conflict of Interest to the PHS funding agency or other PHS-compliant sponsor.

For any Financial Conflict of Interest that the College reports to a PHS agency or other PHS-compliant sponsor, the College shall provide to the PHS awarding agency or other PHS-compliant sponsor an annual Financial Conflict of Interest report that addresses the status of the conflict and any changes to the management plan, for the duration of the project. The annual report shall specify whether the Financial Conflict of Interest is still being managed or explain why it no longer exists. The College must provide annual reports to the PHS awarding agency or other PHS-compliant sponsor for the duration of the project period (including extensions with or without funds).

Within 60 days of determining that a Financial Conflict of Interest exists for a new Investigator who joins an ongoing research activity funded by PHS or other PHS-compliant sponsor, the College must implement a management plan and submit a report to the PHS funding agency or other PHS-compliant sponsor.

In any case in which the Department of Health and Human Services (DHHS) determines that a PHS-sponsored project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by the College as required by this Policy and Federal regulation, the College shall require the Investigator to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

D. Monitoring

The management plan put in place by the College shall specify the way in which the Investigator's compliance with the management plan will be monitored on an ongoing basis until completion of the research project that is funded by PHS or other PHS-compliant sponsor.

E. Retrospective Reviews and Mitigation Reports

When during the course on ongoing research project funded by PHS or other PHS-compliant sponsor, the College identifies a Significant Financial Interest that was not disclosed in a timely manner by an Investigator or which was not previously reviewed, the Designated Official will, within 60 days, review the Significant Financial Interest to determine whether it is related to research activity funded by PHS or other PHS-compliant sponsor, determine whether a Financial Conflict of Interest exists, and if so, implement a management plan on at least on an interim basis.

In addition, whenever a Financial Conflict of Interest is not identified or managed in a timely manner, regardless of whether the Investigator did not disclose an SFI that was later determined to be a Financial Conflict of Interest, or the College did not review or manage the Financial Conflict of Interest, or the Investigator failed to comply with a previously implemented management plan, the College must within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the research funded by PHS or other PHS-compliant sponsor.

- Based on the results of the retrospective review, if appropriate, the previously submitted Financial Conflict of Interest report should be updated to specify the actions that the College will take to manage the identified Financial Conflict of Interest going forward.

The purpose of this retrospective review is to determine if the ongoing research funded by PHS or other PHS-compliant sponsor was biased in its design, conduct or reporting. The College will document the retrospective review; such documentation will include the project number; project title; name of Investigator with the Financial Conflict of Interest; name of the entity with which the Investigator has a Financial Conflict of Interest; the reasons for the retrospective review; detailed methodology used for the retrospective review; findings; and conclusions.

- Based on the results of the retrospective review, if appropriate, the previously submitted Financial Conflict of Interest report should be updated to specify the actions that the College will take to manage the identified Financial Conflict of Interest going forward.

If bias was found during the retrospective review, the College will promptly notify the PHS funding agency other PHS-compliant sponsor and will draft a mitigation report that at a minimum documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines the College's plans to eliminate or mitigate the effect of the bias.

F. Records Retention

Records regarding Disclosures, Designated Official's determinations, COI Committee recommendations, and College actions regarding management of a conflict of interest must be retained by the College for three years beyond the termination or completion of an award, or until resolution of any action by the sponsor involving the records, whichever is

longer. Records relating to unfunded projects need not be retained.

G. Training

Each Investigator, including collaborators, consultants or subcontractors, must complete NIH- compliant training about this Policy (Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Service and PHS-compliant Sponsor Research Awards) and the PHS Conflict of Interest regulations (42 CFR Part 50, Subpart F and 45 CFR Part 94) prior to engaging in research related to any project funded by PHS or other PHS-compliant sponsor and at least every 4 years thereafter, while receiving PHS or PHS-compliant sponsor research funding, and at other times as may be required by the College in accordance with DHHS regulations. For investigators funded by PHS or other PHS-compliant sponsor who are new to the College or who are joining an ongoing research activity funded by PHS or other PHS-compliant sponsor, the College should establish a reasonable, expeditious timeframe when Investigators must complete training.

H. Public Access to Information

The College's Designated Official shall identify the College office and College address as the recipient addresses for public requests for information under the PHS regulations and this Policy, and shall take action necessary to provide reasonable notice of those addresses to the public, including prominently posting this information on the College web site.

The College must respond within five (5) business days to any request for information about Significant Financial Interests held by Key Personnel when the College has determined that the disclosed Significant Financial Interests are related to research funded by PHS or other PHS-compliant sponsor, and constitute Financial Conflicts of Interest. The 5-day response time shall be measured from the date that the request for information is received at the campus-designated address until the date a response is sent to the requestor.

Disclosure forms, Disclosure Update forms, and Management Plans including determinations of Financial Conflicts of Interest under this Policy are public records open to public inspection, under federal law .

I. Sanctions

Failure of an individual to file a complete and truthful financial disclosure for pending proposals, or when a new interest is obtained, or failure to comply with any conditions or restrictions directed or imposed, including failure to cooperate with appointed award monitoring bodies, will be grounds for discipline pursuant to the Saint Mary's Faculty Handbook, section 2.8.4.4, "Unfitness" and/or other applicable employee or disciplinary policies.

Agreements with consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated for cause. In addition, federal regulations may require reports to the federal sponsor of any violations of federal regulations and College policy.

IV. COMPLIANCE AND RESPONSIBILITIES

A. Responsibilities of Investigators, as defined by this Policy:

1. Investigators must disclose to the College all Significant Financial Interests (SFIs) related to the Investigator's Institutional Responsibilities, no later than at the time of application for funding from PHS or other PHS-compliant sponsor.

2. Throughout the period of any PHS or PHS-compliant sponsor research award, Investigators must disclose to the College their SFIs, and those of their spouse or registered domestic partner and dependent children:
   a. Within 30 days of discovering or acquiring any new SFI; and
   b. At least annually throughout the period of the award.

3. Before joining an ongoing research project funded by PHS or other PHS-compliant sponsor, new Investigators must submit a disclosure of Significant Financial Interests to the College.

4. Principal Investigators must fully identify all Investigators on an award who are required to disclose SFIs under the terms of this Policy.

5. Investigators must complete NIH-compliant training about the College's Policy on Disclosure of Financial Interests and Management of Conflicts of Interest for Public Health Service and PHS-compliant Sponsor Research Awards prior to engaging in research related to any project funded by PHS or other PHS-compliant sponsor and at least every 4 years thereafter, while receiving PHS or PHS-compliant research funding, and at other times as may be required by the College under this Policy.

6. In cases where the College has identified a financial conflict of interest held by the Investigator and has implemented a management plan to eliminate, reduce or manage the conflict, Investigators must adhere to the terms of the management plan.

7. Where DHHS determines that a PHS-sponsored project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by the College as required by this Policy and federal regulation, the College shall require the Investigator to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

B. Responsibilities of non-Saint Mary's collaborators, consultants or subcontractors who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a subgrant or subcontract from the College:

1. Must comply with the policies and procedures for disclosure and review of SFIs at the institution at which they are employed, or, if their institution does not have a conflict of interest policy that is PHS-compliant, they must comply with this Policy and campus procedures for disclosure and review of SFIs related to PHS-sponsored awards.

2. Must comply with all requirements of their institution's (or this) policy that pertain to Investigators, including completing NIH-compliant training about the PHS financial conflicts of interest policy prior to engaging in research related to any PHS-funded contract and at least every 4 years thereafter, while receiving PHS research funding.

C. Responsibilities of institutions that receive subawards issued by the College for research funded by PHS or other PHS-compliant sponsor:

1. In cases where the agreement between the College and the subrecipient specifies that the subrecipient's conflict of interest policy shall apply:

    a. Must certify that the subrecipient's conflict of interest policy complies with the requirements of the DHHS regulations.
    b. Must review financial disclosures made by Investigators at the subrecipient institution and, if any Financial Conflicts of Interest are identified, send the College notification of the conflict and of the subrecipient institution's plan to manage, reduce or eliminate the identified conflicts, in accordance with PHS reporting requirements.

2. In cases where the agreement between the College and the subrecipient specifies that the College's conflict of interest policy shall apply, must submit to the College, within the time period specified in its subrecipient agreement with the College, all disclosures by subrecipient Investigators of Significant Financial Interests, for the College's review.

D. Responsibilities of the Business Office:

If an award from PHS or other PHS-compliant sponsor is to be conducted through a subaward, the Business Office must incorporate as part of a written agreement with subrecipients terms that establish whether the Saint Mary's Policy on Disclosure of Financial Interests and Management of Conflicts of Interest for Public Health Service and PHS-compliant Sponsor Research Awards or the policy of the subrecipient (which must be compliant with DHHS regulations) will apply to the subrecipient's investigators.

E. Responsibilities of the COI Committee

The COI Committee must determine whether, based on documentation from a Designated Official, there is a financial conflict of interest, and make a final recommendation to the Designated Official about whether any conditions or restrictions should be placed on the project to eliminate or manage the Financial Conflict of Interest.

F. Responsibilities of Saint Mary's Designated Official(s):

1. A Designated Official must solicit and review Investigators' SFI disclosures for each proposal, progress report, incremental funding or extension, to PHS or other PHS-compliant sponsor, to determine whether there are any SFIs that reasonably appear to be related to the research activity funded by PHS or other PHS-compliant sponsor in which the Investigator is engaged.

2. If an SFI reasonably appears to directly and significantly affect the design, conduct or reporting of the research activity funded by PHS or other PHS-compliant sponsor, a Designated Official shall forward the disclosure and appropriate documentation to the COI Committee for consideration.

3. Upon the COI Committee's determination of a Financial Conflict of Interest, a Designated Official must develop and implement a Management Plan that specifies the actions that have been, and shall be, taken to manage such financial conflict of interest.

   Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:
   - Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
   - For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
   - Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
   - Modification of the research plan;
   - Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
   - Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
   - Severance of relationships that create financial conflicts.

4. A Designated Official must determine, based on final recommendation of the COI Committee, the conditions or restrictions that should be placed on the project to eliminate or manage the Financial Conflict of Interest.

5. A Designated Official must respond within 5 business days to any request for information submitted in accordance with this policy about SFIs held by Key Personnel when the College has determined that the disclosed SFIs are related to the research funded by PHS or other PHS-compliant sponsor and constitute Financial Conflicts of Interest.

6. Prior to the College's expenditure of any funds provided under an award from PHS or other PHS-compliant sponsor (and within 60 days of any subsequently identified financial conflict of interest), a Designated Official must provide to the sponsor an initial report regarding Investigator Financial Conflict of Interest, including financial conflicts of interest of subrecipient investigators in cases where the agreement with the subrecipient institution specifies that they will follow Saint Mary's financial conflict of interest policy.

7. During the period of the award, a Designated Official shall, within 60 days of receipt of disclosure new or newly-discovered SFI, review the disclosure, determine whether it constitutes a Financial Conflict of Interest, and if so, report the Financial Conflict of Interest to the PHS funding agency or other PHS-compliant sponsor. If a Financial Conflict of Interest ceases to exist during the course of the award, updated information

about the status of that Financial Conflict of Interest should be reported to the PHS funding agency or other PHS-compliant sponsor.

8. A Designated Official must provide an annual Financial Conflict of Interest report to the PHS awarding agency or other PHS-compliant sponsor addressing the status of the conflict and any changes to the management plan, for the duration of the project period (including extensions with or without funds).

9. A Designated Official must submit a report to the PHS-funding agency within 60 days of determining that a Financial Conflict of Interest exists for new Investigator who joins an ongoing PHS-funded research activity.

10. If Saint Mary's is a subrecipient of an award from PHS or other PHS-compliant sponsor from another institution, the Designated Official must report to that institution any FCOIs that Saint Mary's identifies for Saint Mary's investigators.

V. PROCEDURES

Procedures are incorporated into the policy text.

VI. RELATED INFORMATION

Policies and Guidance Referenced

- U.S. Department of Health and Human Services (HHS) regulations on conflict of interest:
  - 42 CFR Part 50 Subpart F – Promoting Objectivity in Research, https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F
  - 45 CFR Part 94 – Responsible Prospective Contractors, https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-94
- NIH website on Financial Conflict of Interest, https://grants.nih.gov/grants/policy/coi/index.htm
- U.S. Department of Energy (DOE) Interim Conflict of Interest Policy for Financial Assistance: Financial Assistance Letter No. FAL 2022-02 issued December 20, 2021, https://www.energy.gov/sites/default/files/2021-12/Interim%20COI%20Policy%20FAL2022-02%20to%20SPEs.pdf
- Saint Mary's College of California Faculty Handbook, https://www.stmarys-ca.edu/faculty-handbook
- Saint Mary's College of California Employee Handbook, https://www.stmarys-ca.edu/offices-services/human-resources/employee-resources/handbook
- Saint Mary's College *Policy on Disclosure of Financial Interests and Management of Conflicts of Interest for National Science Foundation Awards,* Office of Research website, Research Compliance page: https://www.stmarys-ca.edu/office-research

VII. FREQUENTLY ASKED QUESTIONS

Not Applicable

VIII. REVISION HISTORY

This policy is a revision of the *Policy on Disclosure of Financial Interests and Management of Conflicts of Interest for Public Health Service and PHS-compliant Sponsor Research Awards*, effective December 14, 2022 through February 20, 2026.

- Presented to Saint Mary's Academic Senate, February 20, 2026
- Revised by the Office of Research, February 8, 2026
- Adopted by Saint Mary's Academic Senate, December 14, 2022
- Drafted by the Office of Research, October 31, 2022