

Office of Research Compliance and Integrity Conflicts of Interest and Commitment Procedures and Guidance
Title: <i>Procedures for Reporting Conflicts of Interest and Commitment in Research and Sponsored Activities</i>
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Acronyms

COC	Conflict of Commitment
COI	Conflict of Interest
CSCE	Center for Scholarly and Creative Excellence
FCOI	Financial Conflict of Interest
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
NIH	National Institutes of Health
NSF	National Science Foundation
ORCI	Office of Research Compliance and Integrity
OSC	Others Significant Contributors
OSP	Office of Sponsored Programs
PD	Project Director
PHS	Public Health Services
PI	Principal Investigator
RIO	Research Integrity Officer
SBIR	Small Business Innovation Research
SFI	Significant Financial Interest
STTR	Small Business Technology Transfer
TCO	Technology Commercialization Office

Background

Grand Valley State University allows and encourages faculty and staff members to participate in outside activities and relationships that enhance the mission of the University. All faculty and staff members are to act with honesty, integrity, and in the best interest of the University when performing their duties, and to abide by the highest standards of research, educational, professional, and fiscal conduct. When faculty and staff pursue outside activities related to their University responsibilities, real and perceived potential conflicts of interest (COIs) and commitment (COCs) are inevitable. Outside activities should not, however, interfere with an individual's University obligations. Faculty and staff must not use their official University positions or influence to further gain or seek advancement for themselves, parents, siblings, spouse or partner, children, dependent relatives, or other personal associates, at the expense of the University.

The requirement to disclose actual and perceived conflicts of interest and commitment related to research and sponsored activities administered by the Center for Scholarly and Creative Excellence (CSCE) is outlined in [GVSU Policy SLT 3.4](#). This policy is applicable only to CSCE-related activities; note that academic/ administrative units may require additional disclosure and conflict management than is mandated by SLT 3.4.

Sponsor requirements for tracking COIs and COCs vary widely. This guidance document has been developed to provide further clarification regarding who is required to submit a disclosure for CSCE-administrated activities under Policy SLT 3.4, and to outline the procedures to follow for the reporting, review, and management of such disclosures. Specifically, the procedures herein apply to externally-sponsored funding applications and agreements administered by the CSCE (e.g., sponsored program submissions, service agreements, testing agreements, educational affiliation agreements, material transfer agreements, data use agreements, research collaboration agreements, and non-disclosure agreements). Note that the Public Health Services (PHS) and the National Science Foundation (NSF) have additional reporting and training requirements that must be followed, as outlined below.

Definitions

1. **Investigator:** Any person, regardless of title or position, who has independent responsibility for some aspect of the design, conduct, or reporting of research, scholarly, or educational activity. Investigators include Principal Investigators, Co-Investigators, and all other individuals identified in the grant application, grant budget, progress report, or any other report submitted to the sponsor by GVSU, if the individual contributes to the development or execution of a project in a substantive, measurable way, whether or not they request compensation. This definition extends to such personnel from external, collaborating entities that have agreed to follow GVSU's COI/COC policy as a condition of a subrecipient agreement (subaward or subgrant).
2. **Institutional responsibilities:** An Investigator's responsibilities on behalf of the University, such as research, scholarship, teaching, and institutional committee memberships.
3. **Family member:** A spouse, domestic partner, dependent child, and/or any other individual with whom a GVSU employee has a close, continuing personal or business relationship with, where the GVSU employee has actual knowledge that the individual is likely to, or will, benefit from a particular University transaction.
4. **Management plan:** A written agreement between the Investigator and the University that outlines how the actual or perceived conflict of interest will be managed.
5. **Independent Monitor:** An identified GVSU employee who is responsible for providing independent oversight of work conducted by an Investigator on an approved management plan.

Procedures

A. Disclosure

- a. Who is required to submit a disclosure?
 - i. All Investigators on externally-sponsored funding applications and agreements administered by the CSCE (e.g., sponsored program submissions, service agreements, testing agreements, material transfer agreements, data use agreements, research collaboration agreements, educational affiliation agreements, non-disclosure agreements) are required to submit a COI/COC disclosure.
 - ii. Every external funding application and agreement administered by the CSCE must have at least one Investigator identified in the submission materials. This is typically the faculty or staff member overseeing the submission. See the [Principal Investigator Eligibility Policy, SLT 3.11.7](#), for more details regarding research grant submissions.
 - iii. Determining who is considered an “Investigator” is dependent upon the sponsor’s requirements and the individual’s role in the project. Final determination regarding an individual’s classification as an Investigator is determined by the office to which the application was submitted (i.e., Office of Sponsored Programs [OSP] or the Technology Commercialization Office [TCO]).
 - iv. The personnel matrix table below shall be used as a guide to determine which individuals are considered Investigators and are required to submit a COI/COC disclosure. (As a general rule, individuals listed as “Senior Personnel” in NSF budgets and “Senior/Key Person” in NIH budgets will likely require disclosure; individuals listed as “Other Personnel” in NSF and NIH grant budgets will typically not require disclosure.) If there are any questions related to a particular submission, contact the OSP or the TCO, as appropriate.

Personnel Matrix

Title/Role	Require COI/COC Disclosure?	Guidance
Principal Investigator (PI) or Project Director (PD)	Always	
Co-Investigator/Co-PI	Always	
Project Managers/Project Coordinators	Rarely	Project managers and coordinators typically operate under the direction of the PI and do not have independent responsibility for any design, conduct, or reporting of the activity.
Laboratory Managers/Technicians	Rarely	Laboratory managers and technicians typically operate under the direction of the PI and do not have independent responsibility for any design, conduct, or reporting of the activity.

Graduate/Postdoctoral Fellows paid on fellowships	Always	This includes Graduate Fellows on Michigan Space Consortium Grant submissions
Graduate/Postdoctoral Fellows paid on training grants	Never	
Faculty Sponsor for Graduate/Postdoctoral Fellows	Always	
Postdoctorals paid on research grants	Rarely	Postdoctorals (Postdoctoral Research Associates, Postdoctoral Research Fellows, Postdoctoral Fellows, etc.) are typically considered in training and conduct research under the guidance and mentorship of a PI and do not meet the criteria necessary to be categorized as Investigators. Note that Postdoctoral Fellows paid on fellowships and training grants are considered separately above.
Graduate Students	Rarely	Graduate students are typically considered in training and conduct research under the guidance and mentorship of a PI. Note that Graduate Fellows paid on fellowships and training grants are considered separately above.
Undergraduate Students	Rarely	Undergraduate students are typically considered in training and conduct research under the guidance and mentorship of a PI.
Other Significant Contributors (OSC)	Never	These individuals are typically included with "Effort of zero person months" or "as needed." Per NIH, these are not acceptable levels of involvement for those designated as Key Personnel.
Program Evaluators	Never	
Consultants	Rarely	Consultants are individuals who generally provide a 'fee for service' and do not typically conduct research. They may provide insight and expertise to the PI but independently are not responsible for the design, conduct or reporting of research. In

		most cases, they do not meet the criteria of Investigator.
Collaborators (unpaid)	Never	Unpaid collaborators do not contribute measurable effort, and therefore do not meet the criteria of Investigator. They should be included as OSCs.
Collaborators (paid) at GVSU	Rarely	Most paid collaborators at GVSU will generally not meet the criteria of Investigator. However, Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) PIs are considered collaborators while also meeting the criteria of Investigator, and therefore require COI/COC disclosure.
Collaborators (paid) at another institution, including subrecipient PIs and senior/key personnel	Sometimes	Paid collaborators at another institution should be included in the proposal as a subrecipient. Disclosure to GVSU is only required when collaborating entities have agreed to follow GVSU's COI/COC policy as a condition of the subrecipient agreement.

This table is based on the personnel matrix developed by Massachusetts Institute of Technology, and is used with their permission.

- b. What must be disclosed?
 - i. Financial Conflicts of Interest (FCOIs)/Significant Financial Interests (SFIs)
 - 1. The Investigator must disclose the following Significant Financial Interests (SFIs) for themselves and their family members that reasonably appear to be related to the Investigator's institutional responsibilities:
 - a. Salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works) when the aggregated value received from a publicly traded entity during the 12-month period preceding the disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, exceeds \$5,000; and
 - b. Salary or other payments for services, when the aggregated value received from a non-publicly traded entity during the 12-month period preceding the disclosure exceeds \$5,000; and
 - c. Equity interests (e.g., stocks, stock options, or other ownership interests) in a non-publicly-traded company of any value during the 12-month period preceding or as of the date of disclosure; and

- d. Income related to intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights); and
 - e. Monetary resources (any amount) provided by a foreign entity related to the Investigator's institutional responsibilities; and
 - f. Reimbursed or sponsored travel that is related to the Investigator's institutional responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state, or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.
 - i. Travel disclosures must include, at a minimum: the purpose of the trip, identity of the sponsor/organizer, destination, duration, and monetary value, if known.
2. The following are not SFIs and do not require reporting:
- a. Salary, royalties, or other remuneration from GVSU;
 - b. Income from the authorship of academic or scholarly works;
 - c. Income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
 - d. Equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.
- ii. Conflicts of Commitment (COCs)
- 1. The Investigator must disclose COCs for themselves and their family members that reasonably appear to be related to the researcher's institutional responsibilities, **whether paid or unpaid**.
 - 2. Examples of COCs that must be reported include, but are not limited to:
 - a. A position (e.g., board member, director, officer, partner, trustee, employee, consultant, etc.) with a sponsor, vendor, or (sub)contractor
 - b. Participation in foreign/international talent programs
 - c. Appointments, affiliations, or other relationships outside of GVSU with a foreign entity/institution
 - d. Non-monetary resources (e.g., equipment, materials, personnel) that were gifted or loaned, even if only on a temporary basis, that support or are related to the Investigator's GVSU work
 - e. Other support from any foreign entities for University-related activities, including support received in-kind (e.g., scholarships, office/laboratory space, employees)

- c. When must disclosure occur?
 - i. Investigators must have a current (within the last 12 months) COI/COC disclosure form on file with the ORCI prior to the appropriate CSCE office submitting a funding application on the Investigator's behalf, and prior to the University accepting an award from, or executing an agreement with, an external sponsor.
 - 1. Investigators are required to update the COI/COC disclosure form at least annually.
 - 2. Investigators must submit an updated COI/COC disclosure form within 30 days of discovery or acquisition (e.g., through purchase, marriage, or inheritance) of a new or increased COI or COC.
 - 3. Investigators who are new to the institution and have external sponsor support should complete the COI/COC disclosure form immediately upon hire, but no later than within 30 calendar days of their hire date.
 - 4. Investigators who are newly participating in the sponsored activity should complete the COI/COC disclosure form immediately upon joining the activity, but no later than within 30 calendar days of starting the activity.
- d. How is a disclosure made?
 - i. COI/COC disclosures are submitted through the Office of Research Compliance and Integrity (ORCI)'s electronic submission system. The disclosure form shall include direct information, or a link to information, for the following items: GVSU's COI/COC Policy in Research and Sponsored Activities, this Procedures document, the Investigator's disclosure responsibilities, and applicable federal regulation references.

B. Review of Disclosures

- a. If no disclosures are indicated on the form, the completed form is acknowledged by ORCI and no further action is required.
- b. If a disclosure is indicated on the form, the disclosure is reviewed by ORCI and the Research Integrity Officer (RIO) to determine whether:
 - i. The disclosure reasonably appears to be related to the externally sponsored activity (e.g., if the conflict could be affected by the activity, or is in an entity whose financial interests could be affected by the activity); and
 - ii. The interest constitutes a COI/COC (e.g., a conflict that may directly and significantly affect the design, conduct, or reporting of the externally-supported activity).
- c. If the disclosure is either found to not be related to the sponsored activity, or does not involve a potential COI/COC, the determination is documented and the completed form is acknowledged by ORCI. No further action is required.
- d. If the disclosure is determined to constitute an actual or perceived COI/COC, ORCI in conjunction with the RIO will develop and implement a plan to manage the conflict.

C. Management and Monitoring of COI/COC

- a. Prior to expenditure of funds, the RIO, with the support of ORCI, is responsible for development of a management plan including conditions or restrictions to eliminate,

reduce, or manage the COI/COC. The Investigator, Authorizing Official, and others as deemed appropriate by the RIO may also be involved in drafting the plan, including conditions such as:

- i. Public disclosure of the conflict when disseminating project information/results;
 - ii. For research involving human subjects, disclosure of the conflict directly to participants and/or requiring that participation in the recruitment or consent of subjects by a conflicted investigator be prohibited or restricted;
 - iii. Appointment of an Independent Monitor capable of taking measures to protect the design, conduct and reporting of the activity against bias resulting from the conflict;
 - iv. Maintaining copies of the project data with a neutral party;
 - v. Modification of the project plan;
 - vi. Change of personnel or their responsibilities, or disqualification from participating in all or a portion of the activity;
 - vii. Reduce or eliminate the conflict through divestiture, restructuring, or placement in a blind trust; or
 - viii. Modify the terms of written agreements relating to the activity; or
 - ix. Modify or sever relationships that pose a COI/COC.
- b. The management plan is documented in writing and will include the following elements:
- i. Role and principal duties of the conflicted Investigator;
 - ii. Description of the COI/COC;
 - iii. Conditions of the management plan;
 - iv. How the plan is designed to safeguard objectivity in the activity;
 - v. How the plan will be monitored to ensure investigator compliance, including identification of an independent monitor when appropriate; and
 - vi. Any other information relevant to the management of COI/COC.
- c. The conflicted Investigator, Authorizing Official, Independent Monitor when applicable, and the RIO sign the management plan.
- d. A copy of the management plan is forwarded to the appropriate office administering the agreement/award (i.e., the Office of Sponsored Programs [OSP] or the Technology Commercialization Office [TCO]) for purposes of reporting to the sponsor (See Section D).
- e. If the activity involves human subjects research and is subject to oversight by the Institutional Review Board (IRB), the Investigator submits a copy of the approved management plan to the IRB for review with the IRB protocol application. The IRB may impose additional, specific conditions or restrictions to ensure protection of the rights and welfare of research participants, but may not alter the finalized management plan.
- f. The review and management of any COI/COC must be completed prior to expenditure of funds.

D. Reporting to Sponsor

- a. When sponsor notification is required—either through requirements dictated by the sponsor's terms and conditions; local, state, or federal regulations; or outlined as part of the approved management plan—the office administering the award/agreement (i.e., OSP or

TCO) will notify the sponsor per the sponsor's requirements, and within the required timeframe.

b. Additional PHS and NSF Reporting Requirements

- i. PHS and NSF have additional requirements that must be followed. FCOIs associated with activities sponsored by, or funding proposals submitted to, either the PHS or the NSF must be reviewed, managed, and reported to PHS or NSF when necessary, prior to expenditure of funds and within 60 days of any subsequently identified FCOI. The report, submitted by OSP, shall include sufficient information to allow the sponsor to understand the nature of the conflict and appropriateness of the FCOI management plan. The plan shall include:
 1. Project number issued by sponsor;
 2. Project title;
 3. Project director or principal investigator;
 4. Name of investigator with the conflict and the entity involved;
 5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium, etc.);
 6. Value or dollar range of the financial interest, or a statement that value is not readily determined;
 7. Description of how the SFI relates to the funded project and the basis for determining that the SFI conflicts with the project; and,
 8. Description of the key elements of the management plan, as described above.
- ii. On an annual basis, OSP reports to the sponsor the status of any previously identified FCOI and any changes to the management plan.
- iii. OSP submits retrospective review and mitigation reports promptly to the sponsor as necessary.

E. Maintenance of Records

- a. Records related to research, disclosures of COIs, COCs, and related management plans are required to be maintained for a period of three years beyond the end of the award/agreement.
- b. The ORCI is responsible for maintaining the appropriate records related to COI/COC disclosures.
- c. The disclosure and supporting documents filed in compliance with this policy will be maintained as confidential to the extent possible under applicable state and federal requirements, the Michigan Freedom of Information Act, and the Michigan Confidential Research Information and Investment Act.

F. Subrecipient Requirements

- a. Many sponsors, including the PHS and NSF, require the awardee institution to take reasonable steps to ensure that any subrecipient complies with FCOI requirements.
- b. **Additional PHS and NSF Subrecipient Requirements**
 - i. Subrecipient awards must specify, in writing, whether the FCOI policy of GVSU, or that of the subrecipient will apply to the subrecipient's investigators.

- ii. When the subrecipient's investigators must comply with the subrecipient's FCOI policy, the subrecipient award will certify in writing that the subrecipient's policy complies with PHS, NSF or other applicable sponsor's regulations, and specify the time period to report all identified FCOI to GVSU, in sufficient time to allow GVSU to report any FCOI to PHS, NSF, or other sponsor prior to expenditure of funds by subrecipient.
- iii. When the subrecipient's investigators must comply with the GVSU FCOI policy, the subrecipient award will specify the time period to report all SFI disclosures to GVSU, in sufficient time for review, management and reporting of any FCOI to PHS, NSF or other sponsor prior to expenditure of funds by the subrecipient. In such case, the subrecipient disclosure and review will follow the same process required by GVSU investigators in Sections A and B of this policy.

G. Training Requirements

- a. COI/COC training is available to all GVSU personnel through the ORCI.
- b. **Additional PHS and NSF Training Requirements**
 - i. Investigator training on FCOI, this policy, and their responsibilities regarding disclosure of SFI is:
 - 1. Recommended prior to submitting a proposal to the PHS, NSF, or other applicable sponsors;
 - 2. Required prior to expenditure of PHS, NSF, or other applicable sponsored funds;
 - 3. Required every 4 years during the period of award; and,
 - 4. Required immediately when the FCOI policy is revised such that investigator requirements are affected; an investigator is new to PHS, NSF or other applicable sponsor project; or an investigator is not in compliance with the policy or mitigation plan.
 - ii. Online training modules shall be completed through GVSU's online research training vendor. The principal investigator of each sponsored project is responsible for ensuring that all Other Key Personnel working on the project complete training.

H. Retrospective Reviews and Compliance

- a. If a conflict is not identified or managed in a timely manner due to noncompliance by the investigator or the University (including failure of an investigator to submit a disclosure form in a timely manner, a failure by the University to review a disclosure or manage a conflict in a timely manner, or a failure by an investigator to materially comply with a management plan), the RIO shall, within 120 days from the date the noncompliance was identified, complete a retrospective review of the individual's activities and the project and make a reasonable determination whether there was any bias in the design, conduct or reporting of the project resulting from the disclosure.
- b. The RIO, with the support of ORCI, shall document the following for all retrospective reviews:
 - i. Project number issued by sponsor;
 - ii. Project title;

- iii. Project director or principal investigator;
 - iv. Name of individual with the conflict and the entity involved;
 - v. Reason(s) for the retrospective review;
 - vi. Detailed description of the methodology used for the retrospective review; and,
 - vii. Findings and conclusions of the review.
- c. The retrospective review shall be reported promptly to the sponsor by OSP/TCO.
- d. If a COI/COC is identified in the course of a retrospective review, the RIO, with the support of the ORCI, shall develop a mitigation plan within 60 days. In addition to the elements identified in section C.b, the mitigation plan will also include the following:
- i. The key elements documented in the retrospective review;
 - ii. A description of any impact of the bias on the project; and,
 - iii. The plan to mitigate the effect of the bias.
- e. The RIO is authorized to suspend, for good cause, an ongoing sponsored activity to prevent any probable or continued violations of this policy.
- f. If bias is found, GVSU shall notify the sponsor promptly, and submit a mitigation report. The report is prepared by the Investigator, Unit Head, Appointing Officer, and RIO, with the support of the ORCI, and shall include a description of the impact of the bias on the research and the plan of action to eliminate or mitigate the effect of the bias.
- g. Violations of this policy shall be subject to disciplinary procedures, potentially including sanctions up to and including suspension and termination of employment at GVSU. In addition, any GVSU employee who has received financial benefit from transactions in violation of this policy shall be liable for repayment (to the appropriate entity) of all financial benefits resulting from such violation. Compliance with this policy may also be enforced through the exercise of administrative oversight of funded research and management of GVSU facilities and other property. Such enforcement measures may include, but are not limited to:
- i. Freezing research funds or accounts;
 - ii. Rescinding contracts entered in violation of this policy or state law;
 - iii. Bringing legal action for restitution to the appropriate entity or entities of the amount of financial benefit received by the GVSU employee as a result of their violation of this policy; or,
 - iv. Other appropriate sanctions consistent with GVSU policies and procedures relating to faculty, staff, or students.
- h. **Additional PHS Retrospective Review Requirements**
- i. In any case in which the Department of Health and Human Services determines that a PHS-funded clinical research study whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by a Investigator with an FCOI that was not managed or reported by GVSU as required by the regulation, GVSU shall require the Investigator to:
 - 1. Disclose the FCOI in each public presentation of the results of the research; and,
 - 2. Request an addendum to previously published presentations.

I. Public Accessibility Requirements

- a. This policy and procedure document will be made publicly available on GVSU website.
- b. **Additional PHS and NSF Public Accessibility Requirements**
 - i. PHS, NSF and other applicable sponsors require GVSU to ensure public accessibility of SFI information related to PHS, NSF and other applicable sponsored research, including an obligation to respond to any written request within 5 business days, with information concerning any SFI that meets all the following criteria:
 - 1. The SFI was disclosed and is still held by the Investigator;
 - 2. A determination has been made that the SFI is related to the funded research; and,
 - 3. A determination has been made that the SFI constitutes an FCOI.
 - ii. The information to be made available shall include the investigator name, title and role in research, name of entity involved with the FCOI, nature of the interest, approximate dollar amount of interest, or statement that the value is not readily determined.
 - iii. The information must be made available to the public for a period of 3 years from the date that it was most recently updated.

Guidance

- A. The PHS FCOI regulations are found in the Code of Federal Regulations: [42 CFR 50, Subpart F: Promoting Objectivity in Research](#). For reference, the below list identified the [eight agencies](#) in the U.S. Public Health Service:
 - 1. Agency for Healthcare Research and Quality (AHRQ)
 - 2. Agency for Toxic Substances and Disease Registry (ATSDR)
 - 3. Centers for Disease Control and Prevention (CDC)
 - 4. Food and Drug Administration (FDA)
 - 5. Health Resources and Services Administration (HRSA)
 - 6. Indian Health Service (IHS)
 - 7. National Institutes of Health (NIH)
 - 8. Substance Abuse and Mental Health Services Administration (SAMHSA)
- B. The NSF FCOI policy is found in [NSF Proposal and Award Policies and Procedures Guide, Part II, Chapter IX.A.](#)
- C. Examples of situations in which a conflict with an external entity could reasonably be considered to be related to an Investigator's sponsored activity include, but are not limited to:
 - 1. The external entity sponsors other activities at GVSU in which the Investigator is directly involved
 - 2. The external entity collaborates on or provides materials, products, data or trainee support for the sponsored activity

3. The external entity is a licensee with improvement rights to technology likely to arise from the sponsored activity
4. The Investigator has financial or other interests that could reasonably be considered to have a potential influence on the design, conduct or reporting of the sponsored activity
5. The external entity makes gifts to GVSU that benefit the Investigator's research/scholarship
6. The external entity sponsors or makes a product that is under study in the sponsored activity in which the Investigator is involved
7. The external entity licenses GVSU intellectual property in which the Investigator has a financial interest
8. The external entity is the sole-source provider of materials or services required for the Investigator to conduct the sponsored activity
9. The external entity provides financial support for the Investigator's trainees