# Valparaiso University
# Financial Conflict of Interest Policy and Procedure

Approved by the President's Cabinet on September 17, 2024
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## I. PURPOSE

The purpose of the Financial Conflict of Interest (FCOI) Policy and Procedure is to protect the credibility of Valparaiso University (Valpo) faculty and staff, ensure the public trust and confidence in Valpo's research and educational activities, further the ideals of integrity and ethical behavior, and ensure objectivity in the conduct of sponsored projects, particularly research. Valpo's FCOI Policy and Procedure strives to reduce, manage, or eliminate FCOIs that may affect, or reasonably appear to affect, sponsored projects.

This Policy and Procedure is designed to meet the requirements of Federal regulations regarding institutional responsibilities and Investigator FCOI (42 CFR Part 50 Subpart F for grants and cooperative agreements and 45 CFR Part 94 for contracts) for Public Health Service-funded projects (including the National Institutes of Health). Valpo's disclosure requirements apply to all sponsored projects (whether sponsored by government agencies, foundations, or corporations). This Policy and Procedure is designed to meet the requirements for PHS-funded projects applicable to the grant and cooperative agreement regulation at 42 CFR Part 50 Subpart F. For projects with other funders and when that funder's requirements are more stringent than or different from PHS requirements, that funder's requirements will apply.

## II. DEFINITIONS

A. **Financial conflict of interest (FCOI)** exists when Valpo's Institutional Official or designee reasonably determines that an Investigator's significant financial interest (SFI) is related to a funded project and could directly and significantly affect the design, conduct, or reporting of a Federally-funded project.

B. **Financial interest** means all financial interests that have monetary value, whether or not the value is readily ascertainable.

C. **Institutional Official (IO)** means the individual Valpo designates to be responsible for the review of SFI disclosures. The IO manages the review of Investigator SFIs and FCOIs as outlined in this Policy and Procedure and has the authority to suspend all relevant activities until the FCOI is resolved or mitigated. For the purposes of this Policy and Procedure, the IO is the Assistant/Associate Provost.

D. **Institutional Responsibilities** refers to the teaching, research, service, and administrative activities of an Investigator or Senior/Key Personnel.

E. **Investigator** means the principal investigator and other person responsible for the design, conduct, or reporting of projects proposed to be sponsored or for which funding is awarded. If a project has more than one Investigator, this Policy and Procedure applies to all people acting as

an Investigator. An Investigator may be a Valpo employee or an external collaborator or consultant. The role of Investigator is not determined by the person's title but rather by the person's proposed or actual role on the sponsored project.

F. **Project** means any externally-funded activity such as research (basic, applied, or developmental), instructional or curricular activities, student support or success services, student aid or scholarships, career development, public service/community partnership initiative, or other activity conducted by faculty or staff on behalf of the University.

G. **Senior/Key Personnel** means the principal investigator and any other person identified as senior/key personnel by Valpo in the sponsored project proposal, progress report, or any other report submitted to the funding agency. Note: This term is defined as it relates to Section IX PUBLIC ACCESSIBILITY REQUIREMENTS.

H. **Significant Financial Interest (SFI)** means:
   1. A financial interest consisting of one (or more) of the following interests of the Investigator (and the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities (e.g., teaching, research, service, administration, etc.):
      a. Regarding any publicly traded entity, if the value of any remuneration received during the 12 months preceding the disclosure, and the value of any equity interest during the 12 months preceding or as of the date of disclosure, when aggregated, exceeds $5,000.
      b. Regarding any non-publicly traded entity, if the value of any remuneration received during the 12 months preceding the disclosure, when aggregated, exceeds $5,000 or when the Investigator holds any equity interest in the entity.
      c. Intellectual property rights and interests (e.g., patents, copyrights), upon the receipt of income exceeding $5,000 related to such rights and interests (not reimbursed through Valpo).
   2. The occurrence of any reimbursed or sponsored travel exceeding $5,000 undertaken by the Investigator and related to the Investigator's institutional responsibilities. This includes travel paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. The disclosure requirement **excludes** travel reimbursed or sponsored by U.S. Federal, state, or local governmental agencies, U.S. institutions of higher education, academic teaching hospitals, medical centers, and research institutes affiliated with U.S. institutions of higher education.

   SFI does **not** include the following types of financial interests. Therefore, an Investigator is not required to disclose the following types of financial interests to Valpo:
      a. Salary, royalties, or other remuneration paid to the Investigator by Valpo if the Investigator is currently employed or otherwise appointed by Valpo, including intellectual property rights assigned to Valpo and agreements to share in royalties related to such rights;
      b. Income from seminars, lectures, or teaching engagements sponsored by a U.S. Federal, state, or local government agency, a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education; or
      c. Income from service on advisory committees or review panels for a U.S. Federal, state, or local government agency, a U.S. Institution of higher education, an academic teaching

hospital, a medical center, or a research institute affiliated with a U.S. Institution of higher education.

d. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
e. Ownership interest in the Institution held by the Investigator (if the Institution is a commercial or for-profit organization).

**NOTE:** Requirements for the disclosure of **foreign** financial interests differ from those for domestic financial interests. Investigators must disclose all foreign financial interests (including income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign institutions of higher education or foreign governments (including local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of $5,000).

## III. TRAINING REQUIREMENTS

A. **General Training Requirements.** Investigators must complete FCOI training prior to proposing to engage or engaging in sponsored projects. This training must be completed at least once every four years. The training must be completed immediately if Valpo's FCOI Policy and Procedure changes in a manner that affects requirements for Investigators or if Valpo finds an Investigator to be non-compliant with Valpo's policy or the agreed-upon management plan. For Investigators new to Valpo, training must be completed before the investigator works on the project.

FCOI training consists of reviewing the FCOI Policy and Procedure and completing the Conflict of Interest course provided by the Collaborative Institutional Training Initiative (CITI). On the Disclosure Form that is included in the Grant Proposal Approval Form (GPAF) internal review packet (described below), the Investigator must certify that they have reviewed the FCOI Policy and Procedure. The GPAF packet must also include the Investigator's CITI certificate of completion. Valpo will post this Policy and Procedure and related forms and links on the Office of Sponsored and Student Research website which is publicly accessible.

B. **NIH-Specific Training.** In addition to the General Training Requirements above, Investigators applying for or engaging in NIH-funded projects must also complete the NIH FCOI Training Module.

## IV. DISCLOSURE, REVIEW, AND MONITORING

A. **Disclosure of SFI.** Investigators are required to disclose SFIs according to the following procedure for themselves and for the Investigator's spouse and dependent children:
   1. **Prior to submission of a proposal for an externally-funded project** – The FCOI Disclosure Form is a required part of Valpo's internal review process using the Grant Proposal Approval Form (GPAF). Specifically, a Disclosure Form must be completed and signed by every Investigator that is part of the proposed sponsored project. The Disclosure Form(s) must be included in the GPAF packet which is reviewed by the IO prior to approving the submission of the proposal.

2. **For Investigators with active sponsored projects** – An updated Disclosure Form must be completed annually and submitted to the IO or designee.
3. **In the event that a new SFI is discovered or acquired** – An updated Disclosure Form must be completed within 30 days and submitted to the IO or designee.
4. **New faculty and staff employees who transfer existing sponsored projects to Valpo** – A Disclosure Form must be completed, signed, and submitted to the IO as soon as the process of transferring the existing sponsored project begins and before any work on the project begins.

B. **Review of SFI Disclosures.** The IO or designee will conduct an initial review of all new and updated DSFs to determine whether an Investigator's SFI is related to a sponsored project and if, so, whether the SFI is a FCOI. The Investigator may be involved in determining whether an SFI is related to the sponsored project (numbers 1 and 2 below) but not in the final determination of an FCOI. An Investigator's SFI is determined to be related to a research/sponsored project when it is reasonably determined that the SFI:
   1. Could be affected by the project, or
   2. Is in an entity whose financial interest could be affected by the project.

   A FCOI exists when the IO reasonably determines that the related SFI could directly and significantly affect the design, conduct, or reporting of the project. ("Significantly" means that the financial interest would have a material effect on the project).

C. **Management Plans.** If it is determined that a potential or actual FCOI exists, the Investigator will develop a written Management Plan to reduce, manage, or eliminate the conflict. The plan will be designed to meet applicable legal requirements, facilitate the resolution or management of any conflict, and protect the sensitivity of disclosed information. The plan will be developed in cooperation with the Investigator's Department Chair, Dean, and the IO. If the Investigator is staff, the plan will be developed in cooperation with people with similar positions within Valpo's organizational structure. The Management Plan will be reviewed by Valpo's Conflict of Interest Review Committee (CIRC) which will make a final recommendation to the IO. The CIRC will be appointed by the IO and will consist of three (3) faculty members who have been, or are currently, involved with a sponsored project. The CIRC may recommend that the Management Plan is acceptable as proposed, or suggest conditions or restrictions be imposed to reduce, manage, or eliminate conflicts. These conditions or restrictions include, but are not limited to:
   1. Public disclosure of FCOIs (e.g., when presenting or publishing the project);
   2. Disclosure to others working on the project, to Valpo's Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), etc;
   3. For research projects involving human subjects research, disclosure of FCOIs directly to participants;
   4. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the project from bias resulting from the FCOI;
   5. Modification of the project plan;
   6. Change of Investigator or other personnel, change in responsibilities, or disqualification of personnel from participating in all or a portion of the project;
   7. Reduction or elimination of the SFI; or
   8. Severance of relationships that create financial conflicts.

Once approved by the IO, the Management Plan will be incorporated into a Memorandum of Understanding (MOU) that details the conditions or restrictions imposed upon the Investigator in the conduct of the project and/or the relationship with the business enterprise or entity. The MOU will be signed by the Investigator, the Investigator's Department Chair, Dean, and the IO. If the Investigator is staff, the MOU will be signed by the people with similar positions within Valpo's organizational structure. The MOU must be in place prior to the beginning of work on the project and the expenditure of funds.

If the CIRC determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from an SFI are outweighed by the interests of scientific progress, technology transfer, or public health and welfare, then the CIRC may recommend, to the extent permitted by Federal regulations, that the project go forward without imposing such conditions or restrictions. The IO will make the final decision regarding resolution.

## V. SANCTIONS FOR NON-COMPLIANCE

A. **Investigator Noncompliance.** An Investigator's failure to comply with this Policy and Procedure or an MOU may be subject to sanctions up to and including termination of employment or contractual relationship with Valpo. Valpo will also take action legally required by the funding sponsor and applicable Federal regulations. In addition, the IO or designee will follow Federal regulations regarding the notification of the sponsoring agency which may take action it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved.

B. **Enforcement Mechanisms and Remedies and Noncompliance Specific to NIH**. The provisions in section A apply. In addition,
   1. The IO or designee shall complete and document retrospective reviews within 120 days of Valpo's determination of noncompliance for SFIs when they are:
      a. Not disclosed in a timely manner or
      b. Not previously reviewed or
      c. Whenever an FCOI is not identified or managed in a timely manner, including:
         i. Failure by the Investigator to disclose an SFI that is determined by Valpo to constitute an FCOI;
         ii. Failure by Valpo to review or manage such an FCOI;
         iii. Failure by the Investigator to comply with the FCOI Management Plan.
   2. The retrospective review shall include, at a minimum, the following key elements:
      a. Project number and title;
      b. PD/PI or contact PD/PI if Co-PIs are used;
      c. Name of the Investigator with the FCOI;
      d. Name of the entity with which the Investigator has an FCOI;
      e. Reason(s) for the retrospective review;
      f. Methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed);
      g. Findings of the review; and
      h. Conclusions of the review
   3. The IO or designee will ensure that in any case in which the U.S. Department of Health and Human Services determines that a PHS or NIH-funded research 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 an FCOI that was not managed or reported by Valpo as required by the regulation, Valpo will require the Investigator to:

a. Disclose the FCOI in each public presentation of the results of the research, and
b. Request an addendum to previously published presentations.

## VI. REPORTING

Valpo will report FCOI-related issues to the sponsor of a funded project according to Federal regulations and the funder's requirements.

A. **General Federal Reporting Requirements.** The review of disclosures and development of any necessary management strategies shall be conducted prior to Valpo's expenditure of funds, and within the required timelines of the sponsoring Federal agency for Investigators newly assigned to an existing project or for newly identified FCOIs for existing Investigators. If any identified conflict or noncompliance requires reporting to the sponsoring Federal agency, the IO or designee will provide a report per applicable regulations. Review, determination of whether a conflict exists, the creation and implementation of the Management Plan, and any required reports to the Federal sponsor will occur within 60 days of submission of Valpo's DF.

B. **Reporting Requirements Specific to NIH**. Additions and exceptions to the above practices for NIH-funded projects include:
   1. The IO or designee shall send initial, annual, and revised FCOI reports, including all reporting elements required by the regulation, to the NIH for Valpo and any subrecipients, if applicable. This shall be performed:
      a. Prior to the expenditure of funds;
      b. Within 60 days of identification for an Investigator who is newly participating in the project;
      c. Within 60 days for new, or newly identified, FCOIs for existing Investigators;
      d. At least annually (at the same time as when Valpo is required to submit the annual progress report, multi-year progress report, if applicable, or at the time of extension) to provide the status of the FCOI and any changes to the Management Plan, if applicable, until the completion of the project.
      e. Following a retrospective review (see below) to update a previously submitted report, if new information is discovered following completion of the review.
   2. All original FCOI reports must include sufficient information to enable the NIH to understand the nature and extent of the FCOI and to assess the appropriateness of Valpo's Management Plan. The original FCOI report must be submitted through NIH's eRA Commons FCOI Module by the FCOI Signing Official and include the following elements:
      a. Project number;
      b. PD/PI or Contact PD/PI;
      c. Name of the Investigator with the FCOI;
      d. Name of the entity with which the Investigator has an FCOI;
      e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
      f. Value of the financial interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;

g. A description of how the financial interest relates to the NIH-funded project and why Valpo determined that the financial interest conflicts with the project;
h. A description of the key elements of Valpo's Management Plan, including:
    i. Role and principal duties of the conflicted Investigator in the project;
    ii. Conditions of the Management Plan;
    iii. How the Management Plan is designed to safeguard objectivity in the project;
    iv. Confirmation of the Investigator's agreement to the Management Plan;
    v. How the Management Plan will be monitored to ensure Investigator compliance;
    vi. Other information as needed.

3. Based on the results of a retrospective review, the IO or designee shall notify NIH promptly if bias is found with the design, conduct, or reporting of an NIH-funded project and submit the required Mitigation Report. Per 42 CFR 50.605(a)(3)(iii), the Mitigation Report must include, at a minimum:
    a. Key elements of the retrospective review;
    b. Description of the impact of the bias on the project;
    c. Valpo's plan of action(s) taken to eliminate or mitigate the effect of the bias (e.g., impact on the project, extent of harm done 9including any qualitative and quantitative data to support any actual or future harm); and
    d. Analysis of whether the project is salvageable.
4. Per 42 CFR 50.606(a), the IO or designee will notify NIH promptly if an Investigator (or subrecipient Investigator) fails to comply with this policy or if an FCOI Management Plan appears to have biased the design, conduct, or reporting of the NIH-funded research.

## VII. RECORDKEEPING

The IO or designee will maintain all FCOI-related records pertaining to all Investigator disclosures of SFIs and Valpo's review of and response to such disclosures and all actions taken under this Policy and Procedure, if applicable. Records will be retained for at least three (3) years from the date that the Final Federal Financial Report (or other final expenditure report) is submitted or, where applicable, from other dates specified in 45 CFR 75.361.

## VIII. COLLABORATIVE PROJECTS/SUBRECIPIENT REQUIREMENTS

A. **Collaborative Projects/Subrecipient General Requirements to a Federal Sponsor.** Collaborators/subrecipients from other organizations must either comply with this policy or provide a certification or written agreement that their organizations comply with Federal policies regarding Investigator SFI disclosure and that their portion of the project complies with their institutional policies.

B. **Collaborative Projects/Subrecipient Requirements Specific to NIH.** Valpo is responsible for ensuring any subrecipient's compliance with the regulation and reporting identified FCOIs for subrecipient Investigators. Awardee institutions must incorporate, as part of a written agreement with a subrecipient, terms that establish whether the FCOI policy of the awardee institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements.
    1. Subrecipient institutions that rely on their FCOI policy must report identified FCOIs to the awardee institution in sufficient time to allow Valpo to report the FCOI to the NIH to meet its reporting obligations.

2. Subrecipient institutions that follow with Valpo's Policy and Procedure must submit all Investigator disclosures of SFIs that are directly related to the subrecipient's work for Valpo. The submission of disclosures to Valpo must be in sufficient time to allow Valpo to review, manage, and report identified FCOIs to the NIH.

Valpo is responsible for monitoring the subrecipient's compliance with the FCOI regulation, management plans, and for reporting all identified FCOIs to the NIH.

## IX. PUBLIC ACCESSIBILITY REQUIREMENTS

A. Valpo will make this FCOI Policy and Procedure and related forms and links publicly accessible on the Office of Sponsored and Student Research website.

B. Valpo will make available information concerning identified FCOIs held by senior/key personnel publicly accessible within five business days. The information will:
   1. Include the minimum elements as provided in Federal regulations;
   2. Be posted on the Office of Sponsored and Student Research website or made available within five business days of a written request;
   3. Be updated on the website at least annually and any response to a written request will include the updated information;
   4. Be updated, within 60 days of a newly identified FCOI, on the website and any response to a written request will include the updated information; and
   5. Remain available for three years from the date the information was most recently updated.

## X. CLINICAL RESEARCH REQUIREMENTS

In any case the Department of Health and Human Services determines that a PHS-funded 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 FCOI that was not managed or reported by Valpo as required by the regulation, Valpo must require the Investigator(s) involved to disclose the FCOI in each public presentation of the results of the research and request an addendum to previously published presentations.