GONZAGA UNIVERSITY FINANCIAL CONFLICT OF INTEREST SPONSORED RESEARCH POLICY - <u>https://www.gonzaga.edu/about/offices-</u> <u>services/sponsored-research-programs-office</u>

#### PURPOSE

The highest standards of conduct, honesty, and integrity are expected of all employees of Gonzaga University. It is the obligation of all personnel to avoid involvement in activities which conflict or might appear to conflict, with institutional responsibilities. The Financial Conflict of Interest policy and guidelines contained in this document are intended to help employees avoid involvement in actual or apparent conflicts of interest, and to protect both the employee and the University from potential legal liability, damage to its reputation and financial loss. All potential Conflicts of Interest require disclosure, evaluation, identification, and management of Financial Conflicts of Interest (FCOI) or commitment.

While it is useful to provide basic guidelines to assist employees in assessing potential conflict situations, no list can be so exhaustive as to provide direction for all the variable circumstances which may arise. The personal good judgment of employees is indispensable.

#### BACKGROUND

The University is committed to promoting research integrity and supporting a balance between academic freedom, confidentiality and security in all research, sponsored program, and technology transfer activities occurring under its auspices. Such activities shall be conducted in full compliance with all University policies and applicable federal and state laws pertaining to conflicts of interest.

### POLICY

The University has an institutional responsibility to establish and maintain policies that promote objectivity in the design, conduct and reporting of research activities in accordance with best practices, sponsor requirements, and federal and state law. In accordance with the specific guidelines for sponsored projects outlined in the Gonzaga University Conflict of Interest Policy in Part II of the Policies and Procedures Manual for all GU employees effective <u>Aug. 1, 2021, this policy further expands on the processes and procedures required to comply with the COI policy</u>.

Disclosures shall be submitted in accordance with this Policy and described procedures, to the Sponsored Research & Programs (SRP) Office. Prior to participating in a research or sponsored program, University personnel having a potential Financial Conflict of Interest shall disclose the details to SRP and this information will be reviewed by the designated institutional officer or their delegate. FCOI that cannot be sufficiently reduced, mitigated or eliminated may not be permitted and, as such, the proposed University activity may need to be redesigned to reduce, mitigate or eliminate the FCOI. The research or sponsored program shall not proceed, except as determined by the institutional officer in collaboration with other persons/offices affected, as required to ensure institutional and individual compliance with applicable state and federal requirements.



This policy sets forth procedures and guidelines that are to be followed in resolving actual and potential employee financial conflicts of interest and commitment pertaining to sponsored projects. This policy applies to all sponsored projects funded by (A) commercial sponsors; (B) those federal, and public/private agencies having specific conflict of interest requirements; and (C) subcontracts issued by or to Gonzaga University under its sponsored projects, irrespective of the source of funds.

## SCOPE

All University researchers or sponsored program senior personnel (to include administrators, students, staff, and faculty) participating in the design, conduct or reporting of research and/or sponsored programs to include Investigators, project directors, collaborators, or consultants.

### DEFINITIONS

*Financial Conflict of Interest (FCOI)* is considered a Significant Financial Interest of a researcher that could directly and significantly affect the design, conduct or reporting of research, scholarship, technology transfer and programmatic outcomes.

*Immediate Family* refers to a person's parents, siblings, spouse, domestic partner, children, grandparent, and any equivalent relatives associated by marriage or partnership. It also refers to any individual who resides on a regular basis in the researcher's domicile.

*Investigator* means the project director (PD) or principal Investigator (PI) or any other senior personnel, regardless of title or position, who is responsible for the design, conduct or reporting of research or educational activities funded by external sources, or proposed for such funding, which may include, for example, collaborators or consultants.

*Investigator's University Responsibilities* means an Investigator's professional responsibilities on behalf of the University as outlined in the researchers position description, faculty activity plan or University policies on scholarships such as research, teaching, professional development, creative activities or service.

*Conflict Management Plan* means a written plan instituted by the University for the management, reduction or elimination of a FCOI to ensure to the extent possible that the design, conduct or reporting of research will be free from bias.

*NSF* refers to the National Science Foundation

*NIH* refers to the National Institute of Health

*PHS* means the Public Health Service, an operating division of HHS, and any components of the PHS to which the authority involved may be delegated.

*Senior/Key Personnel* means the PD/PI and any other person identified as Senior/Key Personnel by the University in the grant application, progress report, or any other report submitted by the

University.

*Subrecipient* means an entity in which funding flows from a prime awardee to them as part of the scope of work on the funded project. Prime institution must take reasonable steps to ensure that any Subrecipient senior personnel complies with the same awards and conditions to include the FCOI policy.

### Significant Financial Interest (SFI) is defined as the following:

1. *Financial Interest* consisting of one or more of the following interests of the Investigator (and those of the Investigator's Immediate Family) that has monetary value and that reasonably appears to be related to the Investigator's University responsibilities. See the definition of SFI exclusions for items that may be excluded from determining whether a SFI exists.

a. Regarding any publicly traded entity, a Significant Financial Interest (SFI) exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000 or represents more than a 5% ownership interest in any single entity. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest as determined through reference to public prices or other reasonable measures of fair market value.

b. Regarding any non-publicly traded entities: a Significant Financial Interest (SFI) exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's Immediate Family) holds any equity interest (e.g., stock, stock option, or other ownership interest); venture or other capital financing; OR,

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

2. *Travel:* Senior/Key Personnel to include Investigators and those responsible for the design, conduct and reporting of research Investigator must disclose the occurrence of any reimbursed or sponsored travel (i.e., paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their University responsibilities, provided, however, this disclosure requirement does not apply to travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education. At minimum, the Investigator must disclose the purpose of the trip, identify the sponsor/organizer, destination, and duration. Per the procedures outlined below, the University may request additional information to determine whether or not a Financial Conflict of Interest exists.

3. *Foreign Financial Interests:* It is important to note that disclosure of foreign financial interests differs from disclosure of domestic financial interests. Investigators, including Subrecipient Investigators, must disclose all foreign financial interests (which includes 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 (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

### The term does not include:

- a. salary, royalties, or other remuneration from the institution to the Investigator if the Investigator is currently employed or otherwise appointed by the institution, including intellectual property rights assigned to the institution and agreement to share in royalties related to such rights.
- b. any ownership interests in the proposing institution if the institution is a commercial or for-profit organization.
- c. if the organization is an applicant under the Small Business Innovation Research Program (SBIR) or Small Business Technology Transfer Program (STTR).
- d. income from investment vehicles such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions.
- e. income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities.
- f. income from service on advisory committees or review panels for public or nonprofit entities.
- g. an equity interest that, when aggregated for the Investigator and the Investigator's Immediate Family, meets both of the following tests: (i) does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value; and (ii) does not represent more than a 5% ownership interest in any single entity; or
- h. salary, royalties, or other payments that, when aggregated for the Investigator and the Investigator's Immediate Family, are not expected to exceed \$5,000 during the prior twelve-month period.

### DISCLOSURE

SFI are required to be disclosed within thirty (30) days of acquiring new or increased SFI, within thirty (30) days of joining an ongoing activity, at least annually and as required by the SRP office. Disclosures submitted via the *Disclosure of External Professional Activities (DEPA) and Related Matters Form* are submitted to SRP and must be completed in accordance with sponsor processes, policies and award terms and conditions. *Disclosures, at a minimum, will occur prior* 

to any external funding submission (<u>required no later than at the time of application for NIH,</u> <u>NSF and other federal funders</u>), at any time that Gonzaga and/or Investigator have reason to suspect that a SFI may have occurred, within 30 days of discovering or acquiring a new SFI and annually during the period of funding, if awarded.

# RESPONSIBILITIES

**Researcher/Investigator/Program Director/Senior Personnel** will be responsible for the following:

- Disclose any SFI as defined in this policy to the SRP office and be accountable for any compliance conditions/restrictions imposed by the University as part of the management of actual or potential FCOIs.
- Regularly updating their disclosure status to ensure regulatory compliance as follows:
  - At the time of external funding application
  - If a proposal is funded annually by submitting an updated *DEPA and Related Matters Form* in accordance with university policy, within 30 days of discovering or acquiring a new SFI, and within the specific period identified by the University during the period of award or as indicated by the sponsor, and any annual or updated reports required a spart of an approved Conflict Management Plan.
- Complete FCOI training as part of the required GU Responsible and Ethical Conduct of Research (RECR) requirements and as required by the funding agency. NIH FCOI Training required, in addition to the GU RECR, is available for NIH Investigators at <a href="https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training">https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training</a>.

The **SRP Office** is the primary point of contact for all matters related to this policy and will be responsible for the following:

- Ensure that Senior/Key Personnel on all externally funded proposals complete the *DEPA and Related Matters Form* prior to submission and at a minimum, annually thereafter, once awarded.
- University policy and procedures for FCOI are up-to-date, publicly available and enforceable with applicable federal guidelines, to include the *DEPA and Related Matters Form*, as part of the federally required certification process for grant proposal submission and Subrecipient attestation.
- Coordinate with the Provost's Office or designee to determine how the review process (required within 60 days) and management of potential FCOI will occur.
- Manage all Subrecipient compliance with this policy to include ensuring that Subrecipients are trained regarding the FCOI regulations, disclosure requirements are in place, as well as whether they will follow their own or prime FCOI policy and procedures. If using their own, subrecipients will certify that it complies with FCOI agency regulation, include timely reporting as part of subrecipient agreement and include the ability for the awardee institution to solicit and review subrecipient investigator disclosures.
- Maintain all records of financial disclosures and actions taken to resolve conflict of interest for a minimum of five years after the final expenditure report for the project.
- Require training for Senior/Key Personnel and Investigators for FCOI as determined by the sponsor and as part of the University's RECR procedures.

• Educate faculty and staff on FCOI policy and procedures, as well as ensure updated policy and *DEPA and Related Matters Form* are publicly available on the SRP external and internal facing website for ongoing disclosure as needed.

The **Provost** or designee is the primary administrative designated official for determination if a potential SFI is related to the externally funded research, if SFI could be affected by the research or if SFI could affect the design, conduct or reporting of the externally funded research, as well as management of the review process. The Provost or designee will be responsible for the following:

- Primary point of contact for the ongoing process pertaining to reporting, managing, reducing, or eliminating FCOI's once identified, to include continual monitoring and compliance oversight.
- Make information available to the appropriate awarding agency regarding all conflicting interests identified by the institution and how those interests have been managed, reduced or eliminated to protect the research from bias. This includes any FCOI identified prior to the expenditure of funds, within 60 days of identification of new or newly identified FCOI for new and/or existing Investigators or Senior/Key personnel, and at least annually as part of the progress reporting and to provide updates to status of any currently managed FCOI or changes to management plans, if applicable, until the completion of the project.
- If a University Investigator fails to comply with the Institution's policies regarding disclosure of SFI, failure by the institution to review or manage such a financial conflict interest, or failure to comply with the FCOI management plan and appears to have biased the design, conduct or reporting of the federally-funded research, the Provost or their designee shall promptly complete a retrospective review within 120 days if the Institutions determination of non-compliance. This documentation will include key identifying elements, reasons for the retrospective review, findings, and conclusions of the review.
- Inform each researcher of the applicable regulation, University policy on FCOI and Investigator's responsibilities regarding disclosure of SFIs.
- Develop and maintain adequate enforcement mechanisms and provide employee sanctions or other administrative actions to ensure compliance. Provost or designee will take corrective action and submit a mitigation report to the sponsor if bias is found within the design, conduct or reporting of the federally funded research or if new information is discovered following completion of the review.

### **REVIEW PROCESS:**

Reviews for potential FCOI shall be completed in advance of approval of the related University proposal submission or agreement, performance of any outside activity and in some cases, as required to be completed in advance of expenditure of funds, per sponsor requirements.

Information included as part of the review process will be disclosed only on a need-to-know basis as required to perform the review and evaluation required by this Policy. Individuals and groups that may have access to this information include SRP staff, the Provost or their designee, and any personnel needed to assist in the review process. The University may be required by sponsors or other regulations to make publicly available, any details of identified and managed FCOI. If required, they shall be posted to a publicly available webpage on a routine basis no later than thirty (30) days following the approval of the management plan. This information shall remain available for at least three (3) years from the date the information was most recently updated.

As part of the award process, all senior personnel and/or Investigators on the award and any Subrecipients will be asked if there are any changes to their previously submitted *DEPA and Related Matters Form*. If none have been identified, additional disclosures will be needed if identified after award or disclosed as part of the annual disclosure process. If an FCOI has been identified at this time, the documents will be forwarded to the Provost or their designee to begin the review process. If the Provost's Office determines that an actual or potential conflict of interest exists, they will convene a minimum of at least two additional individuals to form a Conflict of Interest Review Committee (COIRC).

The COIRC will be responsible for developing a Conflict Management Plan which may include investigation and consultation with individuals that the committee considers necessary and appropriate. The plan will include recommended measures that will reduce, eliminate, or effectively manage the FCOI. The final decisions will be made by the Provost or designee with due regard for the committee's recommendations. Investigators may appeal decisions of the Provost or designee but must be filed in writing and received by the Provost's Office within 14 calendar days from the date of the written decision. The Provost or designee's decision at this point is final and no further appeal is available.

## NON-COMPLIANCE ENFORCEMENT

Failure to comply with the disclosure or Conflict Management Plan procedures may result in the following University action:

- 1) Suspension of research until a corrective plan is approved by the COIRC and has been initiated.
- 2) Completion of a retrospective review of the Investigator's activities and a mitigation report submitted to the appropriate agency per regulations and award terms and conditions.
- 3) A report of misconduct to the federal Office of Research Integrity in the case of federally funded research.
- 4) Cancellation of the research project
- 5) University withdrawal of an application or funded project where the Investigator, after the process of appeal, chooses not to comply with the resolution plan adopted in accordance with University policy and if the project cannot otherwise be completed without the Investigator contribution.

### FCOI TRAINING:

The institution is responsible for informing each Investigator and/or Senior/Key Personnel of the Institution's policy on financial conflicts of interest, the Investigator and Senior/Key Personnel's responsibilities regarding disclosure of Significant Financial Interests, and of these regulations. The institution is also responsible for requiring each Investigator or Senior/Key Personnel to complete training regarding the same prior to engaging in research related to any federally funded grant and at least every four years, and immediately when any of the following circumstances apply:

(1) The Institution revises its Financial Conflict of Interest policies or procedures in any manner that affects the requirements of Investigators and Senior/Key Personnel.

(2) An Investigator or Senior/Key Personnel is new to an Institution; or

(3) An Institution finds that an Investigator or Senior/Key Personnel is not in compliance with the Institution's Financial Conflict of Interest policy or management plan.

The Investigator and Senior/Key Personnel are responsible for completing FCOI training as required by Gonzaga's <u>Responsible and Ethical Conduct of Research (RECR)</u> and as required by the funding agency when applicable.

**References and Resources:** 

Gonzaga University Human Resources Policies and Procedures Manual - Conflict of Interest

**Policy** 

Gonzaga University Faculty Handbook, Policies & Procedures <u>310.03-.04 Initial Identification of</u>

Alleged Misconduct

Gonzaga University Faculty Handbook, Appendix 400A, <u>Conflict of Interest Policy Pertaining to</u> <u>Sponsored Projects 10-1-1995</u>

<u>NIH COI resources page</u> – Public Health Service (PHS) regulation, which apply to grants and awards from the National Institutes of Health and other PHS agencies

NSF COI Policy - National Science Foundation regulations for grants and awards

<u>DOE Interim COI Policy</u> – Department of Energy Interim Conflict of Interest Policy Requirements for Financial Assistance (does not apply to Office of Indian Energy or SBIR/STTR – 12/20/2021

NASA COI Policy (Grant Information Circular) – National Aeronautics and Space Administration regulations for grants and cooperative agreements – 8/21/2023 Effective 8/1/2023

EPA Terms & Conditions - <u>https://www.epa.gov/grants/epas-financial-assistance-conflict-interest-policy</u>

2 CFR 200.112 Conflict of Interest <u>https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.112</u> – Federal agencies must establish conflict of interest policies for Federal awards. A recipient or Subrecipient must disclose in writing any potential conflict of interest to the Federal agency or pass-through entity in accordance with the established Federal agency policies.