

George Mason University Procedure for Review and Management of Disclosures Related to External Proposals

General Description:

Investigators who wish to submit proposals for externally funded research must disclose their known Significant Financial Interests (SFIs) as well as those of their spouses and/or dependent children, related to the Investigator's institutional responsibilities.

Definitions:

“Financial Conflict of interest” (FCOI) means a significant financial interest (SFI) directly and significantly affecting the design, conduct, or reporting of the externally funded research.

“Institutional Responsibilities” means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards and Safety Monitoring Boards and other responsibilities as defined by the institution.

“Investigator” means the Principal Investigator, co-Investigator and any other person, regardless of title or position, who is independently responsible for the design, conduct or reporting of externally funded research. The following positions are automatically considered investigators: all faculty positions (tenure track, term, research, and affiliate) and all postdoctoral research fellows. PIs will be responsible for identifying additional individuals serving as investigators on proposals. This will be documented by the use of standard language in the proposal assignment or other written communication issued to the PI during the proposal preparation process.

“Manage” means to take action to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

“Senior/Key Personnel” means the Principal Investigator and any other person identified as Investigators or Senior/Key Personnel by the University in the proposal, progress report, or any other report submitted to the funding agency by the University.

“Significant Financial Interest” means a financial interest consisting of one or more of the following interests of the Investigator (and/or those of the Investigator's spouse and dependents) that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure certification and the value of any equity interest in the entity as of the date of disclosure certification, when aggregated, exceeds \$5,000. 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;

(ii) With regard to any non-publicly traded entity, a 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 (and/or the Investigator's spouse or dependents) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

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

Procedures:

1. **Disclose Personal Interests:** In order for the University to evaluate SFIs to determine if they pose financial conflict of interests (COIs) each Investigator must use the electronic COI system to certify either: (1) that he or she has no SFIs related to his or her institutional responsibilities or (2) that he or she has such interests. If the Investigator has an SFI, the Investigator must disclose:
 - a. Whether the SFI is related to the project he or she is proposing;
 - b. SFI organization name;
 - c. Amount of ownership (as a percentage whenever possible);
 - d. Amount of remuneration during the past 12 months (in ranges);
 - e. Whether there are any business interactions between the SFI organization and the University;
 - f. Role of the investigator in the SFI organization; and
 - g. Steps already taken to manage any conflicts of interest or commitment.

The above certification/disclosure must occur prior to proposal submission by the University and within 30 days of an Investigator acquiring a new SFI.

2. Review of Disclosures:

- a. All disclosures of SFIs will be reviewed by a COI subcommittee consisting of representatives from the Office of Research Integrity and Assurance (ORIA) and the Institutional Compliance Office.
- b. When the subcommittee finds that the SFI disclosed clearly does not relate to the project the investigator is proposing, the subcommittee will approve the disclosure. If the subcommittee believes that the SFI may pose an FCOI, the disclosure will be placed on the next regularly scheduled COI Committee meeting agenda.
- c. If an investigator indicates that the SFI disclosed does relate to the project he or she is proposing, that disclosure will automatically be placed on the next regularly scheduled COI Committee meeting agenda.
- d. The COI Committee will review the disclosures on the agenda and determine whether 1) the SFI does not create a conflict of interest, 2) the SFI does pose a

conflict of interest that can be effectively managed with a management plan, or 3) the SFI does pose a conflict of interest that is unmanageable.

- i. Investigators with SFIs that were determined to not pose a conflict of interest will receive notice to this effect.
- ii. SFIs that were determined to pose a manageable conflict of interest will be referred for development of a management plan.
- iii. SFIs that were determined to pose an unmanageable conflict of interest will not be approved.

3. Management Plans:

- a. Investigators who have SFIs that require management will work with ORIA to create a draft management plan for review by the COI Committee.
 - b. Each draft management plan will be placed on the agenda of the next regularly scheduled COI Committee meeting as an individual agenda item for review.
 - c. In some circumstances, the Investigator may be invited to present their proposed management plan and answer any questions.
 - d. The COI Committee will: 1) Recommend the management plan for approval, 2) Recommend the management plan for approval after minor revisions, 3) Recommend that the management plan be substantially revised then re-reviewed by the committee, or 4) Recommend that the management plan not be approved.
 - e. Management plans must be accepted by the Investigator and any research monitor(s) named in the plan. Management plans must be approved by the Investigator's Dean or Director, and the Vice President for Research, Innovation, and Economic Impact.
- 4. Appeals:** Recommendations by the COI Committee to find a conflict unmanageable or deny a management plan may be appealed to the Vice President for Research, Innovation, and Economic Impact. The Vice President for Research, Innovation, and Economic Impact, in consultation with the Investigator's Dean or Director, may: 1) agree with the recommendation of the COI Committee, 2) request changes to the Investigator's relationship with the SFI organization or the management plan that would make it acceptable, or 3) overturn the decision of the COI Committee and notify the committee and the Provost of the reasons for this decision.
- 5. Notices and recordkeeping:** Fully executed management plans will be stored in the electronic COI system. The fully executed management plan will be accessible to the Investigator, research monitor(s), and Dean or Director.
- 6. Reports to Funding Agencies:** ORIA in collaboration with the Office of Sponsored Programs will provide all required reports to external funding agencies.

Related Forms, Guidance, and SOPs:

Management Plan Template

Responsibility:

Investigators Proposing External Funding
Office of Research Integrity and Assurance
Deans/Directors
Vice President for Research, Innovation, and Economic Impact

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Approved By	Title and Division	Date Approved
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