

Appendix to Financial Conflicts of Interest in Federally-Funded Research

Policy Number 4010

Additional Requirements for Public Health Service Funded Research

Applicability

This Appendix applies to all Investigators funded by the Public Health Service (“PHS”) except SBIR/STTR Phase I applications/awards. It describes George Mason University (“university” or “institution”) procedures to ensure compliance with *42 CFR Part 50, Subpart F – Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought*.

Additional Definition of Significant Financial Interest

In addition to the significant financial interests specified in university Policy 4010, PHS Investigators must disclose the occurrence of 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 their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. In accordance with the university's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

Disclosure and review requirements

Investigators who are planning to participate in any PHS-funded research must disclose significant financial interests at the time of application. Specifically, each Investigator must provide a list of his or her known significant financial interests (“SFI”) (and those of his or her spouse and dependent children) whether or not the value is readily ascertainable that meet either of the following tests:

1. SFIs that reasonably appear to be related to the Investigator’s institutional responsibilities; and

2. Any reimbursed or sponsored travel related to the Investigator's institutional responsibilities; and
3. Any income related to intellectual property rights paid by any source other than the investigator's current institution; and
4. Any amount of equity (stock, stock options, or other ownership interest) in a non-publicly traded entity (such as a start-up company).

Investigators must update all financial disclosures to the institution each year by June 30 and within 30 days of the acquisition or discovery of new SFIs, including new proposed travel.

The SFI must be reviewed by the University Conflict of Interest Committee and a determination made within 60 days of whether the SFI constitutes a FCOI on a sponsored project. The disclosure to NIH must be updated within this time frame.

Training

All individuals serving as Investigators on PHS-funded projects must complete training on Conflicts of Interest prior to engaging in research related to any PHS-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;
- (2) An Investigator is new to an Institution; or
- (3) An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

Public Disclosure of Information

George Mason University will make information concerning identified FCOIs held by Senior/Key Personnel publicly accessible for three years from the date the information was most recently updated, as required by the NIH FCOI policy. The university will respond to requests for information within 5 business days of receipt of a request made to irb@gmu.edu. The information disclosed includes the following:

- Investigator's name;
- Investigator's title and role with respect to the research project;
- Name of the entity in which the SFI is held;
- Nature of the SFI (*e.g.* equity, consulting fees, travel reimbursement, honoraria, etc.;) and
- Approximate dollar value of the SFI (dollar ranges) 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.

Review of Noncompliance with PHS requirements

Whenever the university identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during

an ongoing PHS-funded research project (*e.g.*, was not timely reviewed or reported by a subrecipient,) the designated official(s) shall, within sixty days, perform the following: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so:

(i) Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflicts of interest going forward;

(ii) In addition, whenever a financial conflict of interest is not identified or managed in a timely manner, including failure by the Investigator to disclose a significant financial interest that is determined by the university to constitute a financial conflict of interest, failure by the university to review or manage such a financial conflict of interest or failure by the Investigator to comply with a financial conflict of interest management plan, the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

The Institution is required to document the retrospective review. Such documentation shall include, but not necessarily be limited to, all of the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a financial conflict of interest;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (*e.g.*, methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

Based on the results of the retrospective review, if appropriate, the university will update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to them. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the university's plan of action or actions taken to eliminate or mitigate the effect of the bias (*e.g.*, impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable.) Depending on the nature of the financial conflict of interest, the university may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

In addition, if NIH determines that one of its funded clinical research projects 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 the university, the university shall require the investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

Subrecipient compliance

When the university carries out PHS-funded work with subrecipients, the written agreement with the subrecipient will specify whether they will be relying on their own PHS-compliant financial conflicts of interest policy or on the university's policy.

If relying on their own policy, the agreement will specify time periods for the subrecipient to report all identified financial conflicts of interest to the university. This time period must be sufficient for the university to provide required reports to the PHS. The university will not release funds to the subrecipient until the required financial conflict of interest reports are received.

If a subrecipient chooses to rely on the university's financial conflict of interest policy, this policy will be followed. When the university is a subrecipient, the involved individuals will also follow this policy.