

PHS Funded Research

(updated 5/9/2020)

The procedures described below describe those that will be followed for Public Health Services (PHS) funded research subject to this policy. The procedures to be followed for other sponsored research are described in separate sections that may be found at <https://www.uvm.edu/ovpr/research-integrity-financial-conflict-interest-sponsored-research> under “UVM FCOI Procedures by Sponsor”.

Review of Disclosed Interests

Prior to the expenditure of funds under any PHS-supported research, or within sixty days of the disclosure of a new Significant Financial Interest (SFI) during the course of an ongoing project, including the disclosure of sponsored travel as defined in this policy, the University will undertake the following:

Initial review

The Designated Institutional Official shall initially review all PHS Investigator disclosures of financial interests to determine that the disclosure is complete, that the information disclosed meets the definition of a Significant Financial Interest as per the UVM Financial Conflict in Sponsored Research policy (SFI) and, to determine if the financial interest is related to the Investigator’s research. If this initial review determines that the information disclosed is not a disclosable conflict of interest under this policy, or is unrelated to the research, the Designated Institutional Official will document this determination.

Subsequent review

If, on the other hand, the initial determination is made that the SFI is related to the Investigator’s research, then the Designated Institutional Official will contact the Financial Conflict of Interest Committee and share:

1. The disclosure, including the Investigator’s proposed actions to eliminate, manage or reduce any potential FCOI;
2. Descriptions of the Investigator’s funded research as it relates to the SFI; and
3. A suggested plan for reducing, managing or eliminating the conflict.

The Financial Conflict of Interest Committee members are appointed by the Vice President for Research. The committee shall contain, at a minimum, two members--including representatives from the faculty from a cross section of academic disciplines. The Committee may conduct its business at a convened meeting or electronically. Ad-Hoc members may be added to the Committee by the Designated Institutional Official at his/her discretion.

The Financial Conflict of Interest Committee will reasonably determine whether or not the disclosed SFI represents a FCOI taking relevant factors into account, including

1. The nature, magnitude and stability of the SFI.
2. The likelihood that the research outcome could impact the SFI. For example, is the research so basic that possible research outcomes would require significant further study and development before any impact would become apparent?
3. The Investigator's role in the project and its relationship to the research outcomes, i.e., how likely is it that the Investigator could introduce bias.
4. Other factors the Committee determines to be relevant.

Disposition of Disclosed Interests

If the Committee determines that there is no Financial Conflict of Interest, then the Designated Institutional Official will document this in the disclosure record stored under UVM Click. If the Committee determines there is a FCOI, the Designated Institutional Official, working with the Committee, shall then finalize, in consultation with the Investigator, the conditions or restrictions, if any, which should be imposed by the institution to manage the FCOI (a Management Plan).

Management Plan

Management Plans conditions may include, but are not limited to, any and all of the following actions:

1. Public disclosure of financial conflicts of interest (*e.g.*, when presenting or publishing the research);
2. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
4. Modification of the research plan;
5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
6. Reduction or elimination of the financial interest (*e.g.*, sale of an equity interest); or
7. Severance of relationships that create financial conflicts.

Management Plans will include the following key elements:

1. The role and principal duties of the conflicted Investigator in the research project;
2. Conditions of the management plan;
3. How the management plan is designed to safeguard objectivity in the research project;
Confirmation of the Investigator's agreement to the management plan;
4. How the management plan will be monitored to ensure Investigator compliance; and
5. Other information the University judges to be relevant.

Notifications

The Designated Institutional Official shall document the plan in the disclosure file stored under UVM Click, notify (i) the Investigator and (ii) the immediate supervisor of the Investigator of the plan, and

obtain confirmation that the plan will be followed. The Investigator's immediate supervisor will be responsible for monitoring the Investigator's compliance with the plan as described therein.

If the research involves human subjects, the Designated Institutional Official will notify the reviewing IRB of the FCOI and the management plan that may be followed. The IRB may impose additional requirements to protect the rights and welfare of human subjects.

Monitoring Compliance with Management Plan Conditions

At the time indicated in their Management Plan, those Investigators with FCOIs subject to the conditions of Management Plans will describe how they met the conditions of the plans. The individual entrusted with the responsibility for monitoring the plans will be asked to confirm their oversight and that the plans' requirements were met.

Reporting of Financial Conflicts of Interest

Initial Report

Before the expenditure of any funds under a PHS-supported research award, or within sixty days of the disclosure of a new SFI during the course of an ongoing project, the designated official will report the FCOI to the awarding component in accordance with the agency's protocol for such reporting. The report will include:

1. Project number;
2. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
3. Name of the investigator with the FCOI;
4. Name of the entity with which the Investigator has a FCOI;
5. Nature of the financial interest (*e.g.*, equity, consulting fee, travel reimbursement, honorarium);
6. Value of the financial interest (dollar ranges: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined;
7. A description of how the financial interest relates to the PHS-funded research and the basis for the institution's determination that the financial interest conflicts with such research; and
8. A description of the key elements of the institution's Management Plan.

Annual Report

For any previously reported FCOI related to an ongoing PHS-funded research project, the Designated Institutional Official shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the Management Plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. The Institution shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding

Component.

Retrospective Review

Review:

For PHS funded research, when a retrospective review is called for because of Investigator or institutional non-compliance as specified in this policy, the Designated Institutional Official shall share the following documentation with the Financial Conflict of Interest Retrospective Review Committee:

1. Descriptions of the Investigator's funded research as it relates to the SFI,
2. The current Management Plan, if one is in place, or a suggested plan for reducing, managing or eliminating the conflict,
3. Specific information about how the plan was not followed, if the retrospective review is being conducted because of the Investigator's failure to follow the management plan (e.g., when did the lapse occur, were any parts of the plan followed, and so on).

The members of the Financial Conflict of Interest Retrospective Review Committee shall be at least 2 and will be appointed by the supervisor of the Investigator. The committee will gather any additional information that it judges relevant (the research record, Investigator's research activities to date, opportunity to influence outcome, and so on) and make a reasonable determination as to whether or not research conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. If the ad hoc Financial Conflict of Interest Retrospective Review Committee determines that there was no bias, the Designated Institutional Official will document the determination.

Disposition:

If the ad hoc Financial Conflict of Interest Retrospective Review Committee determines that there was bias, the ad hoc Financial Conflict of Interest Retrospective Review Committee shall describe the impact of the bias on the research record and recommend actions to mitigate or eliminate the effects of the bias. The ad hoc Financial Conflict of Interest Retrospective Review Committee will also recommend a Management Plan for the conflict moving forward, regardless of whether or not the research was biased, to the Designated Institutional Official.

Additionally, if the biased research is clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the Investigator(s) involved will be required to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

The Designated Institutional Official shall document the ad hoc Financial Conflict of Interest Retrospective Review Committee's review and recommendations in a Mitigation Report, described

below, which will become part of the disclosure record stored under UVM Click.

Notifications:

The Designated Institutional Official will send the Report to the Vice President for Research. The Designated Institutional Official shall add the Report to the disclosure record, send the Investigator and his/her immediate supervisor the Report, and obtain confirmation that the plans contained therein will be followed. The Investigator's immediate supervisor will be responsible for monitoring the Investigator's compliance with the plans moving forward.

If the research involves human subjects, the Designated Institutional Official will send the Mitigation Report to the reviewing IRB of the Management Plan. The IRB may impose additional requirements to protect the rights and welfare of human subjects.

Mitigation Report

The Mitigation Report will include the following elements

1. Project number;
2. Project title;
3. PD/PI or contact PD/PI if a multiple PD/PI model is used;
4. Name of the Investigator with the FCOI;
5. Name of the entity with which the Investigator has a FCOI;
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review (*e.g.*, methodology of the review process, composition of the review panel, documents reviewed);
8. Findings of the review;
9. Conclusions of the review;
10. The impact of the bias on the research project, if any;
11. The plan of action or actions taken to eliminate or mitigate the effect of the bias;
12. The actions that will be taken to manage the FCOI going forward.

The Designated Institutional Official shall promptly send the Mitigation Report to the PHS awarding component in those cases where bias is found.

Public Accessibility

Within five business days of any written request, the University, through the Designated Institutional Official, will provide information about SFIs if:

1. The University determines that the SFI is related to PHS-funded research;
2. The SFI was disclosed and still held by key personnel for the research; and
3. The University determined that the SFI is a FCOI. The information provided will include:

PHS Addendum

1. The Investigator's name, title and role with respect to the research project;
2. The name of the entity in which the SFI is held;
3. The nature of the SFI; and
4. The approximate dollar value of the SFI (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).

The University will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty days of the institution's identification of a new FCOI. The University will disclose further information only in response to new written requests.