

### Other Funded Research

(updated 5/9/2020)

The procedures described below describe those that will be followed for externally funded research subject to this policy, but not funded by the Public Health Services (PHS) or the National Science Foundation (NSF). 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 externally-supported research, or within sixty days of the disclosure of a new Significant Financial Interest (SFI) during the course of an ongoing project, the University will undertake the following:

#### *Initial review*

The Designated Institutional Official shall initially review all the Investigator’s 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 does not meet the definition of a Significant Financial Interest, or is unrelated to the research, the Designated Institutional Official will document this in the determination.

#### *Subsequent review*

If, on the other hand, the initial determination is made that the disclosed interest meets the definition of an SFI and 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. 1
2. The likelihood that the research outcome could impact the SFI. For example, is the research so basic

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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 (the 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

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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.

### **Reporting of Financial Conflicts of Interest**

The Designated Institutional Official will report the existence of FCOIs to those funding agencies where regulations require such reporting.

### **Retrospective Review**

#### *Review:*

When the University chooses to conduct a retrospective review 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.

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

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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.
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