PHS Funded Research  (updated 06/25/13)

The procedures described below are 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 below.

See:

Research supported by the National Science Foundation
http://www.uvm.edu/spa/COI/COI_NSf_funded_research_addendum.pdf

All other sponsored research
http://www.uvm.edu/spa/COI/COI_Other_funded_research_addendum.pdf

Review of Disclosed Interests

Before 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 disclosures of financial interests to determine that the disclosure is complete, that the information disclosed meets the policy’s disclosure threshold, and, in consultation with the investigator’s department chair or Conflict of Interest Review Committee member if needed, 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 there may be the potential for a Financial Conflict of Interest (FCOI) covered by this policy, then the Designated Institutional Official will prepare a disclosure packet consisting of:

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; and

3. A suggested plan for reducing, managing or eliminating the conflict.

This packet will be forwarded to an ad hoc Conflict of Interest Review Committee for review and disposition. Committee members are appointed by the Vice President for Research. The Committee shall contain, at a minimum, three members, including representatives from the
faculty from a cross section of academic disciplines and the Designated Institutional Official. The Committee may conduct its business at a convened meeting or electronically.

The Conflict of Interest Committee will reasonably determine whether or not the disclosed SFI represents a FCOI that could directly and significantly affect the design, conduct, or reporting of the proposed sponsored research 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 determination. If the Committee determines that there is a FCOI, the Designated Institutional Official, working with the Committee, shall then finalize, in consultation with the Investigator, and recommend to the Vice President for Research, the conditions or restrictions, if any, that the institution should impose 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 the research is presented or published);
2. For research projects involving human subjects research, disclosure directly to participants of financial conflicts of interest;
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;
4. Confirmation of the investigator’s agreement to the management plan;
5. How the management plan will be monitored to ensure investigator compliance; and
6. Other information the University judges to be relevant.

Notifications

The Designated Institutional Official will notify the University’s Chief Compliance Officer when Management Plans are developed. The Chief Compliance Officer may review and recommend changes to the plan at his/her discretion. The Designated Institutional Official will present the Management Plan for approval to the Vice President for Research. Upon the Vice President’s acceptance of the Management Plan, the Designated Institutional Official shall document the plan, notify the investigator and his/her immediate supervisor 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. The IRB may impose additional requirements to protect the rights and welfare of human subjects.

Monitoring Compliance with Management Plan Conditions

At the time of annual disclosure, those Investigators with FCOIs subject to the conditions of Management Plans will describe how they met the conditions of the plans. Their immediate supervisors with 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 prepare a review packet containing:
1. Descriptions of the investigator’s funded research,
2. The current Management Plan, if one is in place, or a suggested plan for reducing, managing or eliminating the conflict, and
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 packet will be forwarded to an ad hoc Conflict of Interest Review Committee, as described above for review and disposition. 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 research conducted during the period of the noncompliance was biased in its design, conduct, or reporting. If the Committee determines that there was no bias, the Designated Institutional Official will document the determination.

Disposition:

If the Committee determines that there was bias, the 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 Committee will also recommend a Management Plan for the conflict moving forward, regardless of whether the research was biased, to the Vice President for Research.

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 Committee’s review and recommendations in a Mitigation Report, described below, which will become part of the disclosure record.

Notifications:

The Designated Institutional Official will send the Mitigation Report to the Vice President for Research and the Chief Compliance Officer. Upon the Vice President’s acceptance of the Report, the Designated Institutional Official shall add the Report to the disclosure file, 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; and
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 SFI s 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:

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.