

2.12(A) Financial Conflict of Interest Policy for Public Health Service (PHS)-Funded Projects

Note: The following section specifies Plymouth State University's (PSU) policy regarding Financial Conflict of Interest for any Investigator (and his/her spouse or domestic partner and dependent children) who is responsible for the design, conduct, or reporting of research activities in Public Health Service (PHS)-Funded Projects (Small Business Innovation Research (SBIR) Program Phase I projects are exempt). For USNH policy regarding conflict of interest, see section 2.13 Workload, B. Outside and D. Professional Activities of Part-Time Faculty.

A. Statement of Need and Purpose

Grants and externally sponsored research are important aspects of PSU's outreach program. As these activities grow in sophistication and complexity they intersect increasingly with industrial explorations and entrepreneurial ventures, creating for Investigators the potential for conflict of interest.

A Financial Conflict of Interest exists when it can be reasonably determined that an Investigator's Significant Financial Interest (as defined in Section C. below) could directly and significantly affect the design, conduct, or reporting of the PHS-funded research overseen by PSU. Faculty and staff, as project Investigators (Principal Investigator/Project Director, Co-Principal Investigator/Co-Project Director and all key project personnel), of PSU have an obligation to scrupulously maintain the objectivity of their projects and research, avoiding any actual, potential, or perceived conflict of interest.

PSU has developed this policy, for PHS-Funded Projects, to protect the integrity of these programs and to comply with the revised federal regulations. It is the intent and policy of PSU, as an institution of higher education in receipt of Federal funds, to comply with present and future regulations. To that end, this policy is subject to further refinements as other rules are published.

Specifically, the intent of this policy is to identify and eliminate or manage any possible threat to research objectivity at PSU. The main components are disclosure of Investigators' (and his/her spouse or domestic partner and dependent children) Significant Financial Interests to parties who might be affected by the research, and application of methods to minimize or eliminate the risks associated with such connections. It is not meant to discourage, but rather to safeguard the pursuit and dissemination of knowledge.

B. Applicability

This policy becomes effective August 24, 2012 and will be made available via the PSU Office of Sponsored Programs' Web site. This policy applies to any PSU Investigator who is responsible

for the design, conduct, or reporting activities funded or proposed for funding by external funding sources that are governed by the PHS regulations.

Investigators submitting proposals for newly funded projects that are governed by the PHS regulations must ensure that all participants in the project who are responsible for the design, conduct, or reporting of the project submit the proper Financial Disclosure Statement to PSU's Office of Sponsored Programs at the time of application. The Investigator will submit an updated Financial Disclosure Statement annually and within fifteen (15) days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new Significant Financial Interest.

Individuals who come to work on an established project through reallocation of effort, hiring, transfer, promotion, etc., and thereby become responsible for the design, conduct, or reporting of the project, must submit a Financial Disclosure Statement to the PSU Office of Sponsored Programs before beginning work on the project.

1. If the individual and his/her immediate family have no Significant Financial Interests related to the project, work may begin as soon as the null financial disclosure statement is submitted to PSU's Office of Sponsored Programs.

2. If Significant Financial Interests exist, the individual will delay work on the project until the Grants Process Committee (see section E. Review of Disclosures, below) has reviewed and acted upon the information and the individual has agreed to abide by any conditions or restrictions imposed by the Grants Process Committee.

Collaborators, Subcontractors, Subrecipients, and visiting scientists must either comply with this policy or provide certification to PSU Office of Sponsored Programs that their institution is in compliance with pertinent Federal policies and that their portion of the project is in compliance with their institutional policies. Collaborators, Subcontractors, Subrecipients and visiting scientists, who rely on their institution's Financial Conflict of Interest Policy must report identified conflicts of interest to PSU within thirty (30) days to allow PSU to report the conflict to the PHS Awarding Agency to meet reporting requirements.

C. Financial Disclosure

Any PSU Investigator responsible for the design, conduct, or reporting of research activities funded or proposed for funding by a PHS Funding Agency and as overseen by PSU must reveal all Significant Financial Interests that relate to the project, and the Investigator's institutional responsibilities (i.e. an Investigator's professional responsibilities on behalf of PSU). In addition, such information must be disclosed for the Investigator's immediate family, which is defined as his/her spouse or domestic partner and dependent children.

A Significant Financial Interest is defined as:

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse or domestic partner and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(a) With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, 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;

(b) With regard to any non-publicly traded entity, a Significant Financial Interest 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 (or the Investigator's spouse or domestic partner or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

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

2. Investigators also 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 excluded sources explained below.

A Significant Financial Interest does **not** include:

1. Salary royalties, or other remuneration paid by PSU to the Investigator if the Investigator is currently employed or otherwise appointed by PSU;

2. Intellectual Property Rights assigned to PSU and agreements to share in royalties related to such rights;

3. Funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;

4. Income from seminars, lectures, or teaching engagements 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;

5. Income from service on advisory committees or review panels for a federal, state or local government agency, 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; or

6. Travel expenses that are 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.

D. Disclosure Statements

All Financial Disclosure Statements and related documents are considered sensitive information and only those persons involved in the implementation of this policy will have access to such records.

Financial disclosures for PHS-Funded Projects, will be made using the PSU's Financial Disclosure Statement (for PHS-Funded Projects) form. With this form Investigators will either certify that they and their immediate family hold no Significant Financial Interest to the Investigator's research and institutional responsibilities or indicate the existence of Significant Financial Interests and attach a full description and documentation.

Financial Disclosure Statements and any documentation should be submitted in a sealed envelope marked confidential to the PSU Office of Sponsored Programs. The Office of Sponsored Programs will inform PSU Investigators of this requirement. Submission of the Financial Disclosure Statement must be accomplished before a proposal for external funding will be endorsed and forwarded to a PHS sponsor on behalf of PSU.

Investigators are responsible for updating their records of Significant Financial Interest annually during an award period so that accurate current information is on file with PSU at all times. Updated financial disclosure statements must be submitted to the Office of Sponsored Programs within fifteen (15) days of a change in the circumstances surrounding the Investigator's Significant Financial Interests during the funded period of a project or while a proposal is pending.

E. Review of Disclosures

The general purpose of the review process is to help the Investigator and PSU in avoiding threats to research or project integrity while protecting and furthering the research or project goals.

Before an award is accepted, the Vice President for Financial Affairs will review all disclosure statements that indicate the existence of Significant Financial Interests. He/She will refer the statement to the Grants Process Committee, as needed. Members of the Grants Process Committee are: the Provost/Vice President for Academic Affairs, the Associate Vice President

for Academic Administration and Finance, the Associate Vice President for the College of Graduate Studies, the Chair of the Research Advisory Council, and other guests as needed.

The Grants Process Committee will be responsible for determining whether or not an actual, potential, or apparent conflict of interest exists, i.e. whether the Significant Financial Interest of the Investigator could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. The Committee may request additional clarifying information from the individual which will be treated as non-public information to the extent allowed by law. The Grants Process Committee may also solicit from investigators recommendations for conflict management plans.

If an updated Financial Disclosure Statement is submitted during the funded period of a project, the Grants Process Committee will review the new information within thirty (30) days of receipt to determine whether the changed circumstances pose an actual or apparent conflict and to decide what, if any, modification of the conflict management plan (see next section) should be made. Continued participation by the Investigator on the project is contingent upon certification to abide by any new conditions or restrictions imposed by the Grants Process Committee.

If an updated Financial Disclosure Statement is received during the time a proposal is pending, PSU will defer acceptance of the award until the Grants Process Committee has reviewed and acted upon the new information.

F. Management Plans for Conflict

If the Grants Process Committee determines that an actual, potential, or apparent Financial Conflict of Interest exists, it will recommend either refusal of the PHS-funded Project or acceptance with the development and implementation of a management plan that may include, but are not limited to, the following:

1. Public disclosure of Significant Financial Interests;
2. Monitoring of the research by independent reviewers;
3. Disqualification from participation in all or part of the project;
4. Divestiture of Significant Financial Interests;
5. Severance of relationships creating conflict.

In all cases, resolution of the conflict or establishment of an acceptable management plan must be achieved within sixty (60) days of identification of a Financial Conflict of Interest subsequent to PSU's initial report under the award. Annual updates to the management plan will be completed for the duration of the PHS-Funded Project.

G. Appeals

Appeals of the Grants Process Committee's decision may be made to the PSU President, who will consult with the Investigator and the Grants Process Committee and make a final determination within thirty (30) days of the submission of the appeal.

H. Compliance

As part of the Financial Disclosure Statement, each Investigator must certify that if the Grants Process Committee determines that a conflict exists, the Investigator will adhere to all conditions or restrictions imposed upon the project and will cooperate fully within the individual(s) assigned to monitor compliance.

I. Enforcement

Failure to properly disclose Significant Financial Interests, or to adhere to conditions or restrictions imposed by the Grants Process Committee, will be considered a deviation from accepted standards of conducting research or projects at PSU.

Alleged violations of this policy will be investigated by the Grants Process Committee, which will make recommendations for action to the PSU President. Breaches of policy include failure to file the necessary disclosure statements; knowingly filing incomplete, erroneous or misleading disclosure forms; violation of federal guidelines; or failure to comply with procedures prescribed by the Grants Process Committee. If the PSU President determines that the policy has been violated, he/she may impose sanctions including notification of sponsor and termination of award; formal admonition; a letter to the Investigator's personnel file; and suspension of the privilege to apply for external funding.

PSU shall, within 120 days of the Grants Process Committee's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-Funded Project to determine if there was bias in the design, conduct, or reporting of such research. PSU shall document the retrospective review and complete a mitigation report, in accordance with PHS regulations, if bias is found.

J. Records

The Office Sponsored Programs will maintain records of all disclosures and associated activities securely and confidentially.

All records will be maintained for three (3) years following termination or compliance of the projects or resolution of any government action involving the records.

A disclosure of an identified Financial Conflict of Interest (and associated required updates) for a PHS-funded project at PSU will be made publicly accessible, in accordance with the PHS regulations, via the reporting system that is required by the PHS Funding Agency or by a written

response to any requestor within five (5) business days of a request. The disclosure statement and associated information will not be released without notifying the Investigator.

K. Training

Each Investigator who is responsible for the design, conduct, or reporting of research activities in Public Health Service (PHS)-Funded Projects at PSU must complete the approved PSU training program prior to engaging in research or any expenditure of any funds related to any PHS-funded grant or contract and at least every four (4) years thereafter.

An Investigator shall complete the approved PSU training program within thirty (30) days under the following designated circumstances:

1. PSU Financial Conflict of Interest (for PHS-Funded Research Projects) policy is changed in a manner that affects Investigator requirements;
2. An Investigator is new to PSU or to the PHS-Funded Project; or
3. PSU finds an Investigator noncompliant with this policy or management plan.