Whitworth University

Policies and Procedures for Identification and Management of Financial Conflict of Interest When Engaged in PHS and NSF Funded Programs

Introduction
Whitworth University encourages participation in externally funded projects to carry out its educational mission. Participation in projects and activities funded by grants and contracts is important to the free exchange and development of new ideas, information, materials, and technologies benefiting the university, its students, and the community at large. In these activities, the university endeavors to maintain the highest standards of integrity and ethics. This includes the identification and management of actual and potential conflicts of interest that could bias the design, conduct, or reporting of results of such projects.

In direct response to congressional mandate, officials with the Public Health Service (PHS) and the National Science Foundation (NSF) developed an “objectivity in research and investigator financial disclosure policy” that impacts federal sponsorship of activity from their agencies. The final rules and regulations were released on July 11, 1995, in the Federal Register (Vol. 60, No. 132) and are contained in 42 CFR Part 50 and 45 CFR Part 94 Additionally the policy has been revised affective August 23, 2012.

In addition, the university recognizes the standards set forth by the AAUP for preventing conflicts of interest in government-sponsored research and incorporates those standards by reference in so far as they are in concert with with federal policy (See Appendix A).

The policies and procedures, contained herein, are designed to address the necessary identification and management needed to insure compliance with federal regulations relating to financial conflicts of interest.

Policy
It is the policy of Whitworth University that any employee responsible for the design, conduct, or reporting of a sponsored project under the auspices of the university and funded with federal funds must disclose significant personal financial interest related to that project. If the university determines that such an interest might reasonably appear to be directly and significantly affected by the sponsored project, the university will take steps to either manage or to eliminate the conflict of interest in accordance with a conflict of interest resolution plan submitted by the affected principal investigator(s) and approved by the university’s Conflict of Interest Review Committee.

Applicability
This policy applies to the principle investigator and any other person regardless of title or position, who is responsible for design, conduct, or reporting of research funded by PHS or NSF including sub-grantees and includes basic and applied research and training grants. The policy does not apply to STTR and SBIR applications.

Definitions
The term investigator includes the principal investigator, program director, co-investigator, and any other persons, including outside contractors and consultants, who are responsible for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding, by an external sponsor.

A Financial Conflict of Interest means a Significant Financial Interest that could directly and significantly affect the design conduct, or reporting of PHS and NSF funded research.

Significant Financial Interest” refers to anything of monetary value whether the value is readily attainable or not that could directly and significantly affect the design, conduct or reporting of PHS and NSF funded research. SFI consists of one or more of the following of the investigator (spouse and dependent children) that reasonably appears to be related to the investigators institutional responsibilities:

i. 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;

ii. 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 dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

iii. (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests. This does not include any income received from Whitworth University for intellectual property rights assigned to Whitworth based on agreements to share in royalties related to such rights.

d. Any occurrence of reimbursed or sponsored travel related to your institutional responsibilities must also be disclosed, including instruction, research or service to Whitworth University with the exception of any travel reimbursed or sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center or a research center affiliated with an institution of higher education. Travel that is reimbursed by Whitworth University from a sponsored fund account whose sponsor is an entity that is not one of these exempt entities shall be treated as a Significant Financial Interest. The Investigator must disclose the purpose of the trip, the identity of the sponsor and/or program organizer, the destination and its duration. Additional information, including the estimated cost of travel, may be requested by the RIO and must be furnished upon request/ SFI does not include:

i. Salaries and royalties or other remuneration paid by the institution;

ii. Income from teaching engagements, lectures, etc. sponsored by government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with the institution of higher education;

iii. Income from service on advisory committees or review panels for federal, state, local, agencies or institutes of higher education and their affiliates.

iv. Income from investment vehicles such as mutual funds or retirement accounts, as long as the investigator does not directly control investment decisions made in these vehicles.

Travel expenses means those expenses for travel that are either reimbursed or expended by an outside entity. These expenses must be disclosed at any value.

Manage means taking action to address on FCOI, which can include reducing or eliminating the FCOI, to ensure to the extent possible that the design, conduct and reporting of research.

Senior Key Personnel means the principle investigator and any other personnel identified in the grant application that are responsible for design, conduct and reporting of the grant activities.

Investigator Disclosure
Each investigator is responsible for compliance with the policy, completion of training module if necessary, and must disclose to the university, prior to the time a proposal is submitted, the nature of any reportable Significant Financial Interest, whether or not the value is ascertainable, and the names of entities that would reasonably appear to be directly and significantly affected by the proposed research, educational, or service activities.

The investigator is required to provide this information on behalf of his or her self, spouse, and dependent children in the aggregate. The disclosure must be updated within 30 days as new Significant Financial Interests are acquired during the period of an award and at least annually. The annual review date is one year from the original disclosure.
Reporting Significant Financial Interests
Each investigator must report using the SFI Disclosure Form
1) all significant financial interests related to an investigator’s institutional responsibilities whether or not the income is from a for profit or non-profit, and
2) all significant financial interests in entities whose financial interests would reasonably appear to be affected by such responsibilities, if they meet the following criteria:
• there is an equity interest that, when aggregated for the investigator, the investigator’s spouse and dependent children, exceeds $5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, or
• there are salary, royalties, and other payments that when aggregated for the investigator, the investigator’s spouse and dependent children exceeds $5,000 over a 12 month period prior to application.
• the value of stock options must be disclosed annually or as new stock is accumulated. Documentation needed to determine value will be determined by the institution.
• the value of travel that is reimbursed or paid by sponsor if related to institutional responsibilities. Travel reimbursements or expenditures must be updated within 30 days of the travel.

Training
Investigators must complete training in Conflict of Interest provided by the university prior to engagement in research and at least every four years thereafter. Training must be undertaken immediately if the university policy is changed, if the investigator is new to the university, and/or if an investigator is not in compliance with the policy or a management plan

Determining Conflicts of Interest
The RIO shall review each disclosed SFI; determine whether such SFI relates to federally-funded research, and, if so relate, determine whether a Financial Conflict of Interest (as defined below) exists; and determine what conditions or restriction, if any should be imposed by the institution to manage, reduce, or eliminate such conflict of interest.
The RIO may, depending on the scope of the potential conflict, request that additional staff or faculty serve on an ad hoc review committee to assist in its timely review.

Managing Conflicts of Interest
If it is determined that there is a conflict of interest, conditions or restrictions may be imposed to manage, reduce, or eliminate actual or potential conflicts of interest. This may include, but is not limited to those conditions identified under the following section on Conflict of Interest Resolution Plan.

The following is applicable to NSF funded projects only. If a determination is made that imposing conditions or restrictions would be either ineffective or inequitable; and that the potential negative impacts arising from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health or welfare, the Interim Provost may allow the NSF supported research, educational, or service activities to go forward without imposing such conditions or restrictions, when permitted by applicable regulations.

Investigator Responsibility
Investigators will be held accountable for disclosure of any significant financial interest as defined in this policy and for compliance with any conditions and restrictions imposed by the university in order to manage any actual or potential financial conflicts of interest.

Procedures
Preliminary Discussions
Prior to writing a proposal, the investigator is encouraged to consider whether financial conflicts of interest may exist. A review of the situation with the director of Sponsored Programs during proposal development may help identify an actual or potential conflict of interest. Once identified, the chair or dean may be able to recommend conditions to manage or eliminate the conflict of interest. Based upon this exchange, the chair or dean may endorse (i.e., signature on Section B of the Significant Financial Interest Disclosure Form) a proposal submission, assuming that it will be possible to develop and execute, prior to any expenditures on an award, a conflict of interest resolution plan to manage or eliminate the conflict of interest. Involvement by the chair and/or dean is recommended to make proposal development and processing expedient. An investigator is not required, however, to seek advice from the
chair or dean prior to engaging in the official disclosure process. The investigator may choose instead to consult informally with the director of Sponsored Programs or the chair of the Conflict of Interest Review Committee before filing a disclosure.

**Executing the Significant Financial Interest Disclosure Form and Supporting Documentation and Records Retention**
The investigator shall complete a Significant Financial Interest Disclosure Form, and attach, when appropriate, supporting documentation that identifies the relevant enterprises and the nature and amount of investigator financial interest. The disclosure form and any supporting documentation must be submitted to the Sponsored Programs Office, prior to submittal of the proposal to the funding agency. The Sponsored Programs Office will maintain all records of financial interest disclosure, including the conflict resolution plans. Records for funded projects will be maintained throughout the project period and for an additional three years beyond the end of the project period in accordance with federal regulations.

**Sponsored Programs Office Review**
Upon notification of a grant award from a sponsored program, the Director shall review in collaboration with the Associate Provost for Faculty Development and Scholarship (Research Integrity Officer) the financial interest documentation to determine whether the disclosed interests and relationships of the principal investigator could affect the design, conduct, or reporting of the sponsored project. If the initial judgment is made that an actual or potential conflict of interest exists, the Provost will be notified.

**Conflict of Interest Review Committee**
When the Provost concurs with the judgment that an actual or potential conflict of interest exists, the RIO will establish and Conflict of Interest Review committee from suggestions submitted by the Whitworth University Faculty Executive Committee. The committee shall be composed of three faculty members, of which one member serves as chair. The Sponsored Programs director will serve as an additional nonvoting member of the Committee. The university will determine that a conflict exists, if the research could affect the value of the SFI or the entity in which is there is a SFI. A FCOI exists when a SFI could directly and significantly affect the design, conduct, or reporting of the research.

Reporting directly to the Provost, the Committee shall review all pertinent documentation including, but not limited to, the grant proposal, the Significant Financial Interest Disclosure Form, and the conflict interest resolution plan developed and presented by the investigator in consultation with the chair or dean. At its discretion, the Committee may request additional information from and/or an interview with the investigator whose significant financial interest is under review. The resolution plan will be developed in accordance with University policy on remuneration for extended service. The resolution shall not include any reduction in an employee’s salary unless the plan also includes a leave of absence from the university. Furthermore, in setting the salary of an employee, no account shall be taken of any payments received by any employee from outside sources that are disclosed in connection with the employee’s disclosure of any conflict of interest.

The Committee may endorse the resolution plan developed by the investigator without change or propose alternative conditions which may be either more or less stringent or restrictive. The investigator may propose, or the Committee may require one or more of the following as part of the resolution plan:
- No action beyond disclosure to the university, sponsor, and/or competitor, as appropriate;
- Disclosure of significant financial interest to the (i) academic and professional communities in presentations and publications, (ii) the sponsor through written notification, and (iii) the participants through informed consent documents when human subjects are involved. In determining an appropriate means of disclosure, consideration should be given to whether it should be written and/or oral and to the level of detail.
- Monitoring of research by independent reviewers – either through an in-house quality assurance program or through an outside referee or coordinating center;
- Modification of the research plan by developing a means to manage concerns of bias through establishing protocols that include actions such as blinding, modifying the scope of the project, and setting timetables for the delivery of the product. These modifications would require the approval and cooperation of the sponsor and perhaps collaborating investigators at the university and elsewhere;
- Disqualification of the investigator form participation in all or a portion of the research where no other resolution is acceptable to the investigator and the Conflict of Interest Review Committee;
• Designation of a co-investigator (peer or superior) who has no significant financial interest in the project to assume the lead role on the project;
• The sale or other divestiture of the significant financial interest in a sponsor or competitor and restrictions on re-investment after the project is competed for an appropriate period to provide for publication and critique of the project;
• Placing interest in escrow for the term of the project and perhaps a period beyond the end of the project to provide for publication and critique of the project;
• Severance of other relationships with the sponsor or competitor that create actual or potential conflicts of interest; or
• Other strategies that may include variations of options presented, combinations of options, and/or new options not identified herein.

The Committee shall recommend to the Provost what conditions and restrictions, if any, should be imposed by the university to manage the actual or potential conflict of interest. The final decision regarding management of the conflict of interest shall be made by the Provost with due regard for the Committee’s recommendations. The investigator shall indicate in writing acceptance of the resolution plan prior to expenditure of any funds under the award.

Appeals
Investigators may appeal decisions of the Conflict of Interest Review Committee and the Provost. In such cases, the appeal may be reviewed through the faculty grievance procedure. The appeal shall be filed within 20 days of the contested decision and the Faculty Affairs Committee shall reply within 20 days after receiving the appeal.

If the university is unable to arrive at a satisfactory resolution of the conflict of interest, the director of Sponsored Programs shall inform the granting agency, if required by federal law. The university shall withdraw applications for funding in all cases where the investigator, after the process of appeal, chooses to not comply with the resolution plan adopted in accordance with the policy and procedures if the project cannot otherwise be completed without the services of that investigator.

Potential Sanctions for Failures to Address Conflicts of Interest
An investigator who violated the Policies and Procedures for Managing Conflict of Interest for projects funded by the PHS, the National Institutes of Health and the National Science Foundation or other external sponsors shall be subject to disciplinary action as allowed for in the faculty handbook. In addition, any substantiated non-compliance with the conflict of interest policies and procedures after a grant award has been made will result in a suspension of the affected project and reporting to the funder.

Reporting
The university must report to the awarding agency prior to expenditure of funds the details of each FCOI for its investigators and subrecipients, including the name of the individual with the FCOI, the name of the entity in which the investigator has the financial interest, the nature and magnitude (within ranges) of the interest, the basis for the FCOI determination, and the key elements of the management plan. For an investigator new to the project, reporting must occur within 60 days; for newly identified FCOI’s within 60 days. Disclosures must be renewed and reported annually. Certain details of each FCOI must also be made available to the public on the university’s website (applies only to senior key personnel).

Agreements with Subrecipients
In each contract with a subrecipient, the university will include terms that establish whether the FCOI policy of the awardee institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements. Subrecipient institutions who rely on their FCOI policy must report identified FCOIs to the awardee institution in sufficient time to allow the awardee institution to report the FCOI to the awarding agency.

Retrospective Review
When a disclosure is received late or the review is delayed and the financial interests are related to the research and constitute an FCOI, the university is required to conduct a retrospective review to ascertain whether there has been
bias in the design, conduct or reporting of the ongoing research. The retrospective review does not have to be reported to the funding agency. If bias is found, the institution must prepare a mitigation report and submit it to the awarding agency. The report must outline the action that will be taken to eliminate or mitigate the effect of the bias and report the affect the bias has had on the research project.

Public Accessibility
This policy must be posted on the university’s website in a place that is accessible to the public. Additionally, certain information about each identified FCOI must also be posted. The information must be updated in a timely manner.

APPENDIX A
AAUP Standards for Preventing Conflicts of Interest in Government-Sponsored Research at Universities

A. Conflict Situations
1. Favoring of Outside Interests. When a university staff member (administrator, faculty member, professional staff member, or employee) undertaking or engaging in government-sponsored work has a significant financial interest in, or a consulting arrangement with, a private business concern, it is important to avoid actual or apparent conflicts of interest between government-sponsored university research obligations and outside interests and other obligations. Situations in or from which conflicts of interest may arise are:
   a. the undertaking or orientation of the staff member’s university research to serve the research or other needs of the private firm without disclosure of such undertaking or orientation to the university and to the sponsoring agency;
   b. the purchase of major equipment, instruments, materials, or other items for university research from the private firm in which the staff member has the interest without disclosure of such interest;
   c. the transmission to the private firm or other use for personal gain of government-sponsored work products, results, materials, records, or information that are not made generally available (this would not necessarily preclude appropriate licensing arrangements for inventions, or consulting on the basis of government-sponsored research results where there is significant additional work by the staff member independent of the government-sponsored research);
   d. the use for personal gain or other unauthorized use of privileged information acquired in connection with the staff member’s government-sponsored activities (the term “privileged information” includes, but is not limited to, medical, personnel, or security records of individuals; anticipated material requirements or price actions; possible new sites for government operations; and knowledge of forthcoming programs or of selection of contractors or subcontractors in advance of official announcements);
   e. the negotiation or influence upon the negotiation of contracts relating to the staff member’s government-sponsored research between the university and private organizations with which the staff member has consulting or other significant relationships;
   f. the acceptance of gratuities or special favors to employees of the sponsoring government agency, under circumstances which might reasonably be interpreted as an attempt to influence the recipients in the conduct of their duties.
2. Consulting for Government Agencies or Their Contractors. When the staff member engaged in government-sponsored research also serves as a consultant to a federal agency, such conduct is subject to the provisions of the Conflict of Interest Statutes (18 U.S.C. 202-209 s amended) and the president’s memorandum of May 2, 1963, Preventing Conflicts of Interest on the Part of Special Government Employees. When the staff member consults for one or more government contractors or prospective contractors, in the same technical field as the staff member’s research project, care must be taken to avoid giving advice that may be of questionable objectivity because of its possible bearing on the individual’s other interests. In undertaking and performing consulting services, the staff member should make full disclosure of such interests to the university and to the contractor insofar as they may appear to relate to the work at the university or for the contractor. Conflict-of-interest problems could arise, for example, in the participation of a staff member of the university in an evaluation for the government agency or its
contractor of some technical aspect of the work of another organization with which the staff member has a
consulting or in an evaluation of a competitor to such other organization.

B. University Responsibility
Each university participating in government-sponsored research should make known to the sponsoring
government agencies:
1. the steps it is taking to ensure an understanding on the part of the university administration and staff
member of the possible conflicts of interest or other problems that may develop in the foregoing types of
situation, and
2. the organizational and administrative actions it has taken or is taking to avoid such problems, including:
   a. accounting procedures to be used to ensure that government funds are expended for the
      purposes for which they have been provided, and that all services which are required in return
      for these funds are supplied;
   b. procedures that enable it to be aware of the outside professional work of staff members
      participating in government-sponsored research, if such outside work relates in any way to the
      government-sponsored research;
   c. the formulation of standards to guide the individual university staff members in governing
      their conduct in relation to outside interests that might raise questions of conflicts of interest;
      and
   d. the provision within the university of an informed source of advice and guidance to its staff
      members for advance consultation on questions they wish to raise concerning the problems that may or do
      develop as a result of their outside financial or consulting interests, as they relate to their participation in
      government-sponsored university research. The university may wish to discuss such problems with the
      contracting officer or other appropriate government official in those cases that appear to raise questions
      regarding conflicts of interest.

The above process of disclosure and consultation is the obligation assumed by the university when it accepts
government funds for research. The process must, of course, be carried out in a manner that does not infringe on the
legitimate freedoms an flexibility of action of the university and its staff members that have traditionally
characterized a university. It is desirable that standards and procedures of the kind discussed be formulated and
administered by members of the university community themselves, through their joint initiative and responsibility,
for it is they who are the best judges of the conditions which can most effectively stimulate the search for knowledge
and preserve the requirements of academic freedom. Experience indicates that such standards and procedures
should be developed and specified by joint administration-faculty action.