

# WHITWORTH COLLEGE

## Policies and Procedures for Managing Conflict of Interest for NSF, PHS, and Other Externally Sponsored Projects

### Introduction

Whitworth College 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 College, its students, and the community at large. In these activities, the College 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) have 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. In addition, the College 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 federal policy (See Appendix A). In recognition of the receipt of funding from the National Science Foundation, Whitworth College has adopted the policies and procedures contained herein. The policies and procedures are designed to address the necessary identification and management needs to insure compliance with federal regulations relating to conflicts of interest.

### Policies

It is the policy of Whitworth College that any employee responsible for the design, conduct, or reporting of a sponsored project under the auspices of the College must disclose significant personal financial interest related to that project. If the College determines that such an interest might reasonably appear to be directly and significantly affected by the sponsored project, the College 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.

### 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.

“Significant Financial Interest” refers to anything of monetary value including, but not limited to, salary and other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights) of the investigator and the investigator’s spouse and dependent children. A “significant financial interest” does not include:

- salary, royalties, or other remuneration from Whitworth College;
- income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- income from service on advisory committees or review panels for public or non-profit entities;
- an equity interest that, when aggregated for the investigator, the investigator’s spouse, and dependent children, does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value and constitute more than a 5% ownership interest in any single entity; or
- salary, royalties or other payments that when aggregated for the investigator, the investigator’s spouse, and dependent children over the next twelve months are not expected to exceed \$10,000.

A “potential conflict of interest” occurs when there is a divergence between an individual’s private interests and his or her professional obligations to the College such that an independent observer might reasonably question whether

the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. An "actual conflict of interest" depends on the situation and not on the character or actions of the individual. For purposes of this policy, a conflict of interest exists when the College, through procedures described herein, reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the educational, research, and/or service activities that are funded or proposed for funding.

### **Investigator Disclosure**

Each investigator must disclose to the College, prior to the time a proposal is submitted, the nature of any reportable significant financial interest and the names 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 and is required to update this information as new significant financial interests are acquired during the period of an award. Significant financial interest of the investigator, the investigator's spouse, and dependent children which are unrelated to the proposed externally supported research, educational, or service activity and the entity to which the financial interests are applicable need not be disclosed.

### **Reporting Significant Financial Interests**

Each investigator must report 1) all significant financial interests that would reasonably appear to be affected by the research, educational, or service activities funded, or proposed for funding, by an external sponsor, and 2) all significant financial interests in entities whose financial interests would reasonably appear to be affected by such activities, 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 \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value or constitutes more than a 5% ownership interest in any single entity; or
- there are salary, royalties, and other payments that when aggregated for the investigator, the investigator's spouse and dependent children exceeds \$10,000 over a 12 month period.

### **Determining Conflicts of Interest**

The ultimate responsibility for review of significant financial interest disclosures, determination that actual or potential conflict of interest exists and determination of what conditions or restrictions if any, should be imposed by the College to manage, reduce, or eliminate conflict of interest rests with the Academic Vice President.

### **Managing Conflicts of Interest**

Conditions or restrictions may be imposed to manage, reduce, or eliminate actual or potential conflicts of interest. This may include, but are not limited to those conditions identified under the following section on Conflict of Interest Resolution Plan. If the College finds that it is unable to manage satisfactorily an actual or potential conflict of interest, the Academic Grant Writer will be responsible for informing the PHS or NSF sponsor. (Note: currently only these two sponsors have regulations requiring reporting, however, Whitworth College has determined that the College policy will be applied to all sponsored programs.).

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 Academic Vice President 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 College 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 a financial conflict of interest may exist. Review by the department chair and/or college dean of the relevant financial information at an early stage of 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 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 Academic Grant Writer 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 Office of the Academic Grant Writer, prior to submittal of the proposal to the funding agency.

If the investigator completes Section B of the form to declare a reportable significant financial interest, the supporting documentation will be placed in an envelope marked confidential and submitted with the disclosure form to the Office of the Academic Grant Writer with an endorsement by the investigator's department chair. College administrators will respect the investigator's privacy and limit disclosure within the tenets of the federal law. The Office of the Academic Grant Writer will maintain all records of financial interest disclosure, including the conflict resolution plans. Confidential information submitted for projects, which are not funded, will be returned to the investigator unopened or destroyed as requested by the investigator. Records for funded projects will be maintained throughout the project period and for an additional six 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 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 Academic Vice President will be notified.

## **Conflict of Interest Review Committee**

When the Academic Vice President concurs with the judgment that an actual or potential conflict of interest exists, the case will be referred to the Conflict of Interest Review Committee. The President, from suggestions submitted by the Whitworth College Faculty Exec, will appoint this three-member committee, of which one member serves as chair. Each member will serve a two-year term. The Sponsored Programs director will serve as an additional non-voting member of the Committee.

Reporting directly to the Academic Vice President, the Committee shall review all pertinent documentation including, but not limited to, the grant proposal, the Significant Financial Interest Disclosure Form, and the conflict of 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 College 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 College. 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 College, 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 College and elsewhere;
- Disqualification of the investigator from 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 completed 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 Academic Vice President what conditions and restriction, if any, should be imposed by the College to manage the actual or potential conflict of interest. The final decision regarding management of the conflict of interest shall be made by the Academic Vice President 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 Academic Vice President. 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 College is unable to arrive at a satisfactory resolution of the conflict of interest, the Academic Grant Writer shall inform the granting agency if required by federal law. The College 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 public Health Service 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.

## 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 Contractions.* 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 and 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.