Shepherd University
Faculty Conflict of Interest in Research Policy

Introduction

Shepherd University recognizes that externally funded research can play a key role in supporting the scholarly efforts of faculty. The ability of faculty members to secure grants and contracts will allow them to pursue scholarly endeavors that support the mission of Shepherd University in many different ways. As research activities have the potential to intersect with business and industry, it is crucial that potential or perceived conflicts of interest are avoided. In fact, Shepherd University’s Faculty Handbook states that: *Faculty and all employees must avoid any outside employment or for-profit enterprise which might create any form of professional conflict of interest.* (Faculty Handbook section 23.A.4). The following policy will clarify this language in the Faculty Handbook.

A conflict of interest will exist if the personal concerns of a faculty member directing or participating in a sponsored research project directly and significantly impact, or reasonably would be objectively perceived to directly and significantly impact, the research activities associated with that sponsored project. Research activities involve all aspects of a research project and include but are not limited to the development of hypotheses or theses, experimental design, experimental methodology, data collection and analysis, and reporting of results. It is incumbent upon any faculty, staff, or student conducting research to avoid a conflict of interest and be able to document this fact.

In addition to ensuring compliance with policies adopted by both the National Science Foundation (NSF) and Public Health Service (PHS), this policy will safeguard the integrity of sponsored research at Shepherd University. This policy will achieve these goals by identifying and either managing or eliminating the risks to research integrity resulting from a conflict of interest.

Policies related to conflict of interest and disclosure of such were adopted by both the NSF and the PHS, U.S. Department of Health and Human Services on 1 October 1995. These policies, while separate, are similar in scope and established a series of requirements that colleges and universities receiving federally funded grants must meet. These requirements include the need to:

a. develop, enforce, and certify to PHS and NSF an institutional policy ensuring that PHS- or NSF-funded research is not biased by investigators' conflict of interests;
b. inform potential investigators of the policy and their responsibilities under the policy;
c. designate institutional officials charged with soliciting and reviewing disclosure statements from each investigator planning to participate in NSF- or PHS-funded research;
d. provide guidelines that enable both designated officials and researchers to identify conflicts of interest and take action to manage, reduce, or eliminate the conflict; and,
e. establish a repository to maintain records for the required time (at least three years from the date the final grant expenditures report is submitted) of all disclosures and any and all actions taken by the institution associated with conflict of interest.
1.0 General Overview of Conflict of Interest in Research

1.1 Definition of Conflict of Interest in Research

A number of definitions exist as to what constitutes a conflict of interest. Simply put, a conflict of interest results when the concerns of any member of a research team (faculty, student, staff, or outside collaborative partner or subcontractor) have a direct and significant impact on the research activities associated with that sponsored project. Further, a conflict of interest is any situation, whether compensated or uncompensated, in which a university employee’s intellectual independence or the university’s integrity would be compromised as a result of decisions made in the process of conducting research or in those activities associated with research. The existence of a conflict is not determined by the subjective intentions of the employee or student involved, but rather is established by a reasonable person standard as defined in case law. A conflict of interest arises in, but is not limited to, the following circumstances:

1.1.1 When the personal or business interests of the researcher, including the interests of his/her relations and associates, conflicts with the researcher’s obligations to the University, including respect for the University’s policies and students, or staff, under his/her supervision;

1.1.2 When, without prior written agreement, use is made of University resources, including secretarial, office and administrative services, technical services, laboratories, premises, logo, insignia, for the personal gain or benefit of the researcher or for the gain or benefit of others related to or associated with the researcher.

1.1.3 When the work of students is directed or done with a view to benefiting the personal or business purposes of the researcher, his/her associates or relations, to the detriment of the University and/or to students’ academic progress.

1.1.4 When the personal or business interests of the researcher, his/her associates or relations compromise the independence and impartiality necessary to perform his/her duties.

1.1.5 When a researcher uses confidential information that is gathered in the course of his/her duties for personal or business gain or for the gain of his/her associates or relations.

1.1.6 When, in the course of his/her duties, a researcher incurs an obligation to an individual or business that is likely to benefit from special treatment or favors granted by the researcher or the University.

1.1.7 When a researcher accepts an executive appointment, employment, or shares in any non-university organization that might reasonably expect him/her to disclose confidential or proprietary information to which they have access by virtue of his/her University appointments.

1.2 Definition of Researcher/Investigator

A researcher/investigator is defined as any person (faculty, student, or staff member) who is responsible for any aspect of the research project. This would include anyone involved in designing or conducting experiments, collection or analysis of data, data reporting, and/or preparation of any publications or presentations resulting from the research. Anyone receiving compensation or
volunteering his/her time to allow for the research to be completed is potentially a researcher/investigator and must disclose any potential conflict of interest.

1.3 Definition of Financial Interest
As the majority, but not all, potential conflicts of interest will involve potential or perceived financial benefits or conflicts, it is important to define a financial conflict of interest. Simply put, a financial interest is defined as anything of monetary value. Examples of financial interest include:

- a. salary or other payments for services (i.e., honoraria or consulting fees);
- b. equity interest (i.e., ownership interests, stock options, stocks);
- c. intellectual property rights (i.e., copyrights, patents and royalties from these rights); or
- d. services or favors in lieu of direct compensation.

Excluded from financial interest are the following:

- a. salary, royalties, or other remuneration from Shepherd University;
- b. any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;
- c. income from seminars, lectures, or teaching engagements sponsored by the University;
- d. income from service on advisory committees or review panels for public or nonprofit entities;
- e. an equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both or the following tests: does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity; provided that the equity interest is not likely to be directly affected by the outcome of the research; or
- f. salary, royalties or other payments that when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed $10,000 during the next funded 12-month period, as to income not likely to be directly affected by the research.

If any of the compensation received by an investigator as described above in either (d) or (f) is dependent upon a particular outcome of a sponsored research project, then these would be considered as a financial interest.

2.0 Disclosures

2.1 Requirements for Disclosure
In order to ensure that those members of the Shepherd University community engaging in research are in full compliance with federal regulations, all researchers must disclose any significant financial interests:

2.1.1 That an uninterested party could reasonably see as being positively or negatively impacted both directly and significantly by the educational activities or research if such activities are funded or proposed for funding by an external sponsoring agency.

2.1.2 In any business, corporation, or other entity that would have financial interests that could reasonably be seen as being either positively or negatively impacted by the educational activities or research if such activities are funded or proposed for funding by an external sponsoring agency.
2.2 The requirements listed above are considered by Shepherd University to be the minimum for disclosure. The University recognizes that a researcher may deem that it is in his or her best interest to voluntarily disclose other potential conflicts of interest, financial or not, that could be reasonably perceived by others to constitute a conflict of interest. Shepherd University urges all researchers to consider that disclosure of potential conflicts of interest is crucial in ensuring that allegations of misconduct do not damage the reputation or career of the researcher or bring negative attention to Shepherd University.

3.0 Procedure for Disclosure

3.1 Every researcher with a conflict of interest as described above is required to complete a Conflict of Interest Disclosure Form (Appendix A) and attach all of the required supporting documents. Once completed, this form and the supporting documents are to be submitted with a copy of the research proposal or application for funding to the executive director(s) of the Shepherd University Research Corporation (SURC). The completed form and supporting documents are to be submitted in a sealed envelope marked “CONFIDENTIAL.”

3.2 Any and all conflicts of interest are required to be disclosed prior to proposal submission. During the course of the award, it is the responsibility of the researcher to update his or her documents annually or more frequently if there is a change in the financial interests of the researcher.

3.3 The SURC executive director(s) will complete the initial review of the documents and make a preliminary determination if an actual or potential conflict of interest exists.

3.3.1 A conflict of interest will exist if any of the criteria described in section 1.0 are found to be present.

3.3.2 If the SURC Co-Director(s) determines that there is reasonable concern that a conflict of interest or potential conflict of interest may exist, the conflict of interest disclosure form and supporting materials will be referred to a Conflict of Interest Review Committee for action. This review committee will be called to action by the Vice President for Academic Affairs and will be comprised of the SURC executive director not involved in the initial review of the case, the University’s general counsel, one faculty member selected by the Vice President for Academic Affairs, and one faculty member selected by the researcher. In the selection of faculty members, both the Vice President for Academic Affairs and the researcher will each nominate two tenured or tenure track faculty members currently employed at Shepherd University. The researcher will strike one of the names provided by the Vice President for Academic Affairs and the Vice President for Academic Affairs will strike one of the names provided by the researcher.

3.3.3 The Conflict of Interest Review Committee will review the documents and determine what, if any, conditions or restrictions the University will require the researcher to abide by to ensure that the actual or potential conflicts of interest are properly managed. These conditions will be disclosed to the researcher in a written document, the Conflict Resolution Plan. Conditions placed on a researcher may include but are not limited to:

a. Public disclosure of significant financial interests.

b. Monitoring of research by independent reviewers.
c. Modification of the research plan.
d. Disqualification from participation in the portion of the project that is affected by the significant financial interest.
e. Divestiture of significant financial interests.
f. Severance of relationships that create actual or potential conflicts.

3.3.4 The researcher will be given 10 working days to review and comment on the Conflict Resolution Plan. The researcher is allowed to appeal the proposed conditions or restrictions to the President. Any appeal must be filed in writing with the President within 10 working days. The President should consult with the researcher and members of the Conflict of Interest Review Committee prior to making a decision. The decision of the President will be final.

3.4 Once approved, the Conflict Resolution Plan will be signed by both the researcher and the President. The researcher’s signature on the Conflict Resolution Plan provides assurance that the researcher understands and agrees to abide by the conditions and/or restrictions put forth.

3.5 The SURC executive director(s) are responsible for maintaining records and copies of all documents and any Conflict Resolution Plans for no less than five years after the termination of the associated research project whether funding is received for the project or not. If actions are taken by any regulatory agency the SURC executive director(s) will maintain records for no less than five years following the resolution of these actions. All records shall be kept in the strictest confidence and access to these documents will be restricted to:
   a. the researcher,
   b. members of the Conflict of Interest Review Committee,
   c. the President, and
   d. others who have a legal right to review the records.

4.0 Collaborations

4.1 Collaborators
Collaborators are those researchers who are not members of the Shepherd University faculty, staff, or student body. Collaborators may be from other colleges and universities, affiliated with government agencies (local, state, federal), employed by non-governmental organizations, or employed by private businesses.

4.2 Collaborators are required to comply with this policy or provide evidence that their home institution, agency, organization, or business is in compliance with federal conflict of interest policies. Collaborators must also provide assurances that their portion of the research project is in compliance with policies in place at their institution or business. If the institution or private business does not have a conflict of interest policy, a representative of said organization will sign an agreement to abide by the Shepherd University Conflict of Interest Policy.
5.0 Violations and Sanctions

5.1 Violations
Violations of this policy may result in sanctions being imposed on a researcher. Violations may include but are not limited to:

a. Failure to file a conflict of interest form and supporting documentation.
b. Filing a false or intentionally misleading conflict of interest form.
c. Refusal to cooperate with those charged with resolving a potential conflict of interest.
d. Intentionally failing to abide by the terms of the Conflict of Interest Resolution Plan.

5.2 Reporting and Investigation of Alleged Violations
Alleged violations of conflict of interest are to be reported to the Dean of the School of the researcher involved. The Dean will then contact the Vice President for Academic Affairs. Both the Dean and the Vice President for Academic Affairs (VPAA) will ensure that confidentiality is maintained as damage to both the researcher and the individual reporting the alleged violation can come from a breach of confidentiality. Following an allegation of conflict of interest, the VPAA will assess whether there is reasonable concern that a conflict of interest may exist. If there is reasonable concern, the VPAA will form a Conflict of Interest Review Committee as in Section 3.3.2 to investigate the allegations. The Conflict of Interest Review Committee will prepare written recommendations as to whether a conflict of interest occurred and recommended sanctions within 10 working days. This report will be forwarded to the researcher and VPAA for action. The Vice President for Academic Affairs will notify the researcher and President of his/her findings.

5.2 Appeal Process
The researcher has a right to appeal the decision and recommended sanctions of the Conflict of Interest Review Committee. Before any actions are taken in findings of research misconduct, the respondent shall have the right to appeal the university’s decision. All appeal actions must be completed within five working days of the investigation unless an extension has been granted by the VPAA. The researcher must be given sufficient timely notice of the findings to prepare an appeal statement and must be provided with the process for appeal in writing. The Deans’ Council sitting as a body shall be the final appeal authority in cases of research misconduct and will conduct an appeal based on the facts presented to the Investigation Committee. In this matter, the longest serving dean will chair the appeal process. All reasonable steps must be taken to ensure that no member of the Deans’ Council has unresolved personal, professional, or financial conflicts of interest with the researcher or any other parties involved in the alleged conflict of interest. The Deans’ Council will forward the results of the deliberations to the President who will render a decision. The decisions of the President will be final.

5.3 Sanctions
Shepherd University can impose sanctions in keeping with the rights of faculty, staff, and students as described in the Faculty Handbook, the Staff Handbook, and the Student Handbook. The severity of sanctions imposed will depend upon the extent of the violations. Lesser sanctions should be imposed for inadvertent, unintentional, and minor violations. On the other hand, deliberate, knowing and major violations could warrant the severest sanctions allowed. Any sanction must take into consideration the interests of the University, with due regard for academic freedom and the rights of the researcher.