

**BLUEFIELD STATE COLLEGE
BOARD OF GOVERNORS
POLICY NO. RS-804**

TITLE: FINANCIAL CONFLICT OF INTEREST ON FEDERAL GRANTS POLICY

SECTION 1. GENERAL

1.1 Scope: This “Financial Conflict of Interest on Federal Grants Policy” (hereinafter referred to as the "policy") was designed to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by federal grants or cooperative agreements will be free from bias resulting from investigator financial conflicts of interest.

1.1.1 This policy applies to all faculty and other staff involved in federally funded research.

1.1.2 This policy was crafted in response to federal regulations that require all investigators disclose any potential financial conflict of interest to the College prior to undertaking federally funded research.

1.1.3 This policy is applicable to all federally funded sponsored project activity at Bluefield State College including sub-awards and federal flow through projects.

1.1.4 Additionally, all faculty members, non-faculty staff (Covered Employees), and officials of Bluefield State College remain subject to the applicable provisions of the West Virginia Governmental Ethics Act and must also comply with its requirements as set forth in WV Code Chapter 6B, Article One, *et seq.*

1.2 Authority: 2011 Public Health Service (PHS) Regulations: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F); Responsible Prospective Contractors (45 C.F.R. Part 94)

1.3 Filing Date: March 11, 2014

1.4 Effective Date: March 6, 2014

SECTION 2. INTRODUCTION

2.1 All faculty members and non-faculty staff (“Covered Employees”) of Bluefield State College (BSC) are subject to policies concerning conflicts of interest and conflicts of commitment affecting BSC employment and external professional activities. This policy is based on policies and guidelines adopted by federal law and federal agency sponsor

requirements. Any questions regarding this policy should be directed to the Bluefield State College Office of Research and Sponsored Programs (RASP).

SECTION 3. DEFINITIONS

- 3.1. Disclosure of significant financial interests means an investigator's disclosure of significant financial interests (SFI) to Bluefield State College (BSC).
- 3.2. Financial interest means anything of monetary value, whether or not the value is readily ascertainable.
- 3.3. FCOI means financial conflict of interest or more fully described as a significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of federally funded research.
- 3.4. Investigator means the project director (PD) or principal investigator (PI), co-principal investigator (Co-PI), and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of federally funded research, which may include, for example, collaborators or consultants.
- 3.5. Research encompasses any basic and applied research, be it bench work, creative activity (e.g., a published article, book, or book chapter), or product development (e.g., clinical trials, diagnostic test, or drug). As used in this policy, the term includes any such activity for which research funding is available from a federal agency through a grant or cooperative agreement, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, training grant, program project, or research resources award.
- 3.6. Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by BSC in the grant application, progress report, or any other report submitted on the research to the federal funding agency by BSC under the scope of this policy.
- 3.7. Significant financial interest (SFI) means one of the following:
 - 3.7.1 A significant financial interest exists if the following situations apply to the investigator and/or the investigator's spouse or domestic partner as evidenced by registration or certification as a same-sex partner, and dependent children, involving companies that reasonably appear to be related to the proposed research:
 - a. For publically traded companies, if income in excess of \$5,000 (in the aggregate) is received during the twelve months preceding the disclosure. Examples of income include salary, consulting fees and honoraria, paid authorship, stock, stock options, or other ownership interests (based on public prices or other reasonable measures of fair market value).

- b. For non-publically traded companies, if income in excess of \$5,000 (in the aggregate) is received during the twelve months preceding the disclosure, or when any equity interest is held (e.g., stocks, stock options, or other ownership interests).
- c. If any income is received from intellectual property rights and interests (e.g., patents, copyrights).
- d. Any travel paid for by any entity other than a federal, state or local government, an institution of higher education, an academic teaching hospital, a medical center or a research institute associated with an institution of higher education must be disclosed. This disclosure will include, at a minimum, the purpose of the trip, identity of the sponsor/organizer, destination, and duration. In accordance with BSC's FCOI policy, the Director of RASP or their designee will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the federally funded research.

3.8 Significant financial interest does not include the following types of financial interests:

3.8.1 Salary, royalties, or other remuneration paid by BSC to the investigator if the investigator is currently employed or otherwise appointed by BSC, including intellectual property rights assigned to BSC and agreements to share in royalties related to such rights.

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

3.8.3 Income from seminars, lectures, or other teaching engagements, or from service on advisory panels or review panels from a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

SECTION 4. FINANCIAL CONFLICT OF INTEREST COMMITTEE

- 4.1 Membership - This committee will consist of five members appointed by the Provost/VP for Academic Affairs from a list of names of individuals submitted by the Faculty Senate and College Council. All members of the committee are expected to have demonstrated significant grantsmanship. Two of these members should be departmental chairs or center directors. The chair of the committee will be a tenured faculty member at the rank of Professor. The Director of RASP or their designee will serve on the committee in an exofficio capacity.
- 4.2 Duties - This committee will review the FCOI forms and the associated management/monitoring and either accept or suggest modifications to manage or eliminate the conflict. The committee will submit their recommendations to the Director of RASP.

SECTION 5. INSTITUTIONAL RESPONSIBILITIES AND PROCEDURES

- 5.1 Investigator Training - In order to facilitate compliance with the federal policy, BSC is responsible for investigator training, collection and evaluation of FCOI forms, and enforcement of this policy. In addition to making this policy and associated forms available on its web site, training will be provided by RASP for all investigators prior to engaging in federally funded research. Training must be repeated at least every four years, and immediately when BSC revises its FCOI policies or procedures in any manner that affects the requirements of investigators; an investigator is new to BSC; or an investigator is found to be in non-compliance with BSC's FCOI policy or management plan.
- 5.2 Disclosure requirements - At the time of submission of a grant to a federal agency, all participating investigators are required to fill out and submit a FCOI form to RASP which will be reviewed by the Director of RASP (and if a conflict is noted, by the Financial Conflict of Interest Committee). In addition, all investigators must submit an updated FCOI form annually during the period of the award (by deadlines established by RASP) to include any information that was not disclosed previously to BSC, and to include updated information regarding any previously disclosed significant financial interest (i.e., the updated value of a previously disclosed equity interest). Any newly discovered or acquired significant financial interest (i.e., through purchase, marriage, or inheritance) must be disclosed within thirty (30) days.
- 5.3 Subcontracts - If the federally funded research involves a sub recipient (i.e., subcontractors or consortium members), BSC (as the awardee institution) will take reasonable steps to ensure that any sub recipient investigator complies with the federal policies by:
 - 5.3.1 Establishing in writing with the sub recipient whether the financial conflict of interest policy of BSC or that of the sub recipient will apply to the sub recipient's investigators.
 - 5.3.2 If the sub recipient's investigators must comply with the sub recipient's financial conflict of interest policy, the sub recipient shall certify that its policy is in compliance with federal policies. In the absence of this certification, the agreement will state that sub recipient investigators are subject to the financial conflict of interest policy of BSC for disclosing significant financial interests that are directly related to the sub recipient's work for BSC.
 - 5.3.3 Additionally, if the sub recipient's investigators must comply with the sub recipient's financial conflict of interest policy, the written agreement will specify a deadline for the sub recipient to report all identified financial conflicts of interest to BSC

so that BSC can provide timely FCOI reports, as necessary, to the relevant federal agency.

5.3.4 Alternatively, if the sub recipient's Investigators must comply with BSC's financial conflict of interest policy, the written agreement will specify a deadline for the sub recipient to submit all investigator disclosures of significant financial interests to BSC so that BSC can provide timely FCOI reports, as necessary, to the relevant federal agency.

5.3.5 Providing FCOI reports to the federal agency regarding all financial conflicts of interest of all sub recipient investigators consistent with this policy, i.e., prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

5.4 Review of FCOI and management of conflicts - An investigator's significant financial interest is related to federally funded research when BSC reasonably determines that the significant financial interest: 1) could be affected by the research, or 2) is in an entity whose financial interest could be affected by the research. A FCOI exists when BSC reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the federally funded research.

5.4.1 At the time of submission of a grant to a federal agency, all participating investigators are required to fill out and submit a FCOI form along with the proposal and the Proposal/Award Checklist. Signed FCOI forms will be reviewed by the dean or unit director; outcomes may include:

5.4.1.1 If a FCOI form indicates no significant financial interest, the forms can be forwarded directly to RASP along with the proposal.

5.4.1.2 If a FCOI form indicates a significant financial conflict of interest, the proposal will be forwarded on to RASP to meet agency deadlines but with a flag indicating a possible conflict of interest. Financial conflicts of interest will be addressed by one of the following approaches:

a. The dean (or director) will work with the investigator to develop a management plan to eliminate the conflict of interest before the FCOI form is forwarded to RASP. The dean or director will confirm the agreement in writing to the Director of RASP.

b. If it is not possible to eliminate the conflict of interest, a plan to reduce or manage the conflict must be developed by the investigator in consultation with the dean or director with guidance from RASP. This plan will then be forwarded to the Director of RASP who will forward it on to the Financial Conflict of Interest Committee.

5.4.2 All conflicts of interest must be resolved and management plans approved before the research project can begin.

5.4.3 If a disclosure of a new conflict arises or the discovery of an undisclosed conflict is uncovered, the Financial Conflict of Interest Committee will review and make recommendations within sixty (60) days of the new conflict disclosure or unreported disclosure discovery.

5.4.3.1 The Financial Conflict of Interest Committee will review all of the submitted material and either accept or suggest modifications to further eliminate the conflict. This could involve, at either the committee's request or at the investigator's request, a meeting with the committee, involving the dean/director as needed. Expert opinions may also be sought by the committee. The Committee will submit a recommendation to the Director of RASP who will forward it on to the President, Provost/VP for Academic Affairs and the VP for Financial and Administrative Affairs for final approval. Investigators may appeal any final decision in writing within fourteen (14) days.

Examples of approaches that could be used to manage a FCOI include, but are not limited to:

- a. Public disclosure of FCOI (e.g., when presenting or publishing the research).
- b. For research projects involving human subjects research, disclosure of FCOI directly to participants.
- c. 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.
- d. Modification of the research plan.
- e. Change in personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
- f. Reduction or elimination of the financial interest (e.g., sale of an equity interest).
- g. Severance of relationships that create financial conflicts.

5.5 Whenever BSC implements a management plan, BSC will monitor investigator compliance with the management plan on an ongoing basis until completion of the affected federally funded research project. In the event of any significant conflicting financial interest that is discovered subsequent to initial reports to federal agencies, BSC will implement a management plan within 60 days and the Financial Conflict of Interest Committee will complete a retrospective review to determine whether the research was biased relevant to the financial interest of the researcher (i.e., PI/PD) and, if so provide a mitigation report if required by the relevant federal agency.

5.6 Reporting of conflicts - BSC must certify in each application for funding to which this policy applies, that BSC has a written and enforced administrative process to identify and manage financial conflicts of interests and that they will ensure compliance with all such related federal policies regarding FCOI.

- 5.7 BSC must provide initial and ongoing FCOI reports to the federal agency, as required. Thus, BSC is required to maintain records relating to all investigator disclosures of financial interests and BSC's review of, and response to, such disclosures (whether or not a disclosure resulted in BSC's determination of a FCOI) and all actions under BSC's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the federal agency, or as required by the specific agency. BSC must also monitor investigator compliance with approved management plans throughout the duration of the funded project.
- 5.8 Public accessibility to FCOI information - Prior to BSC's expenditure of any funds under a federally funded research project, BSC shall ensure public accessibility via its web site of information concerning any significant financial interest disclosed to BSC that meets the following three criteria:
 - 5.8.1 The significant financial interest was disclosed and is still held by the senior/key personnel as defined by federal policies;
 - 5.8.2 BSC determines that the significant financial interest is related to the federally funded research; and
 - 5.8.3 BSC determines that the significant financial interest is a FCOI.
- 5.9 The information that BSC must make available via its web site will include the following:

the investigator's name; the investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest or a statement that the interest is one whose value cannot be readily determined by normal assessments of fair market value. This posted information must be updated at least annually and will remain accessible for at least three years from the date that the information was most recently updated.
- 5.10 Enforcement - Investigators will not be able to access funds prior to disclosure of a FCOI and approval of a management plan. Noncompliance must also be reported to the appropriate federal funding agency. Certain agencies (e.g., NIH grants for clinical research) require public disclosure of FCOI on all public presentations and publications (including addendums for previously published items) for any funded research that did not comply with federal disclosure regulations.

- 5.11 Failure of investigators to comply with this policy, including restrictions specified by the management plans, will be grounds for discipline and sanctions under the appropriate College policy.

Adapted from Financial Conflict of Interest on Federal Grants Policy, Southern Illinois University, effective date August 24, 2012.