



TITLE: Individual Conflict of Interest	Effective Date: 15-August-2012
POLICY: 001 REVISION: 1	Last Revised: 17-August-2023
SCOPE: This process applies to all Radford University employees	Review Date: 17-August-2024
PURPOSE: This policy summarizes professional conduct standards that relate to objectivity and provides a framework for the review, assessment, and management of external activities that poses a potential conflict of interest in a sponsored project to ensure university-wide compliance with COI directives and establishes standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from an Investigator’s financial conflict of interest (FCOI).	
KEYWORDS: Conflict of interest, COI, FCOI, Significant Financial Interest	
Policy Owner: Sponsored Programs and Grants Management and the Research Compliance Office, Radford University	
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1. Purpose

A conflict of interest (COI) describes a situation in which an individual’s professional judgment is at risk of being biased by a secondary interest, resulting in possible harm or the implication of personal gain. Having a COI does not mean the person is biased or has done something wrong – the term refers to the risk of bias, whether bias or harm have occurred. A COI assessment is a factual evaluation based on the existence of certain parameters that could lead to biased judgement or inappropriate personal gain in university operations such as research, contracting, or purchasing. State law and federal research regulations allow for certain conflicts of interest when specified conditions are met, as outlined in this policy.

In accordance with the Code of Federal Regulations, 42 CFR 50.603-50.604, and the State and Local Government Conflict of Interest Act, as codified in Chapter 31 of Title 2.2 of the Code of Virginia, Radford University is required to manage, reduce, or eliminate any actual or potential conflicts of interest derived from significant financial interest from its employees. The University realizes that certain external activities consistent with the professional expertise of faculty, and consistent with the mission of the university, can enhance professional development and enrich the academic experience of students. While external activities are encouraged by the university, the integrity of the institution as well as the research that is being conducted by the individual faculty members depends on a high degree of transparency and appropriate oversight of relationships with outside entities. Elimination or careful management of disclosed potential conflicts of interest provides the necessary assurance to external sponsors that personal gain has not influenced the design, conduct, or outcomes of the research, nor inappropriately biased decision-making in other university activities.



This policy summarizes professional conduct standards that relate to objectivity and provides a framework for the review, assessment, and management of external activities that poses a potential conflict of interest in a sponsored project to ensure university-wide compliance with COI directives.

It also establishes standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from an Investigator's financial conflict of interest (FCOI). Additionally, this policy safeguards the interests and reputation of Radford University, its faculty and students, and their research.

2. Definitions

1. "Business" (or external entity or organization) means any corporation, partnership, sole proprietorship, firm, franchise, association, trust or foundation, or any individual or entity carrying on a business or profession, whether or not for profit. This definition excludes the University, or any other entity controlled by, or affiliated with the University.
2. "Disclosure" is the full recording or specification of the employee's relationship with an external organization or involvement in external activities.
3. "External Activities" include but not limited to consulting, travel, equitable ownership of a business, spouse and/or family member's equitable ownership of a business, honoraria, paid authorship, remuneration, or other form of salary and royalties.
4. "Faculty Member" is anyone employed by Radford University maintaining faculty status, regardless of rank, appointment as Teaching/Research Faculty, Administrative/Professional, or Special Purpose Faculty. The complete categories of faculty are defined in the RU Faculty Handbooks.
5. "Family Member" means an employee's spouse or immediate family member who is a dependent of the employee (or whom the employee is a dependent).
6. "Institutional responsibilities" are defined broadly and includes, but does not limit, teaching, advising, research and scholarly activities, outreach, administrative and institutional committee service, and service to professional associations or on panels such as peer, institutional, or accreditation review boards.
7. "Investigator" means the Project Director, Principal Investigator, or any other person, regardless of title or position, that is qualified by the university to serve in such role who is responsible for the design, conduct, and reporting of research on a sponsored project.



For the purposes of this policy, collaborators, consultants, or subawardees, are considered Investigators, as is anyone else defined as key personnel in the sponsored proposal and award.

8. “Significant Financial Interest” is defined differently by state law and federal regulation. The Commonwealth of Virginia uses the term “Personal Interest.”
 - a. “Personal Interest” as defined by the Virginia State and Local Government Conflict of Interests Act: a financial benefit or liability accruing to an officer or employee or to a member of his immediate family. Such interest shall exist by reason of (i) ownership in a business if the ownership interest exceeds three percent of the total equity of the business; (ii) annual income that exceeds, or may reasonably be anticipated to exceed, \$10,000 from ownership in real or personal property or a business; (iii) salary, other compensation, fringe benefits, or benefits from the use of property, or any combination thereof, paid or provided by a business or governmental agency that exceeds, or may reasonably be anticipated to exceed, \$10,000 annually; (iv) ownership of real or personal property if the interest exceeds \$10,000 in value and excluding ownership in a business, income, or salary, other compensation, fringe benefits or benefits from the use of property; (v) personal liability incurred or assumed on behalf of a business if the liability exceeds three percent of the asset value of the business; or (vi) an option for ownership of a business or real or personal property if the ownership interest will consist of (i) or (iv) above.
 - b. “Significant Financial Interest” as defined by federal regulation: a financial interest consisting of one or more of the following interests of the investigator and those of the investigator’s spouse and dependent children that reasonably appear to be related to the investigator’s institutional responsibilities:
 - (1) Publicly Traded Entity – a significant financial interest exists if the value of any remuneration received from that entity in the twelve months preceding the disclosure and the value of equity interest in that 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: stock, stock option, or other ownership interest, as determined through public prices or other reasonable measure of fair market value.



- (2) 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 family members hold any equity interest (e.g. stock, stock option, or other form of ownership interest); or
- (3) Intellectual property rights and interest (e.g. patents, copyrights), upon receipt of income related to such rights and interest.

Public Health Service investigators must also 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.) This disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, and institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.

The term significant financial interest does not include the following types of financial interests:

- Salary, royalties, or remuneration paid by Radford University to the Investigator, including intellectual property rights assigned to the institution and agreements to share in royalties related to such rights;
 - 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;
 - Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, and institutions of higher education; or
 - Income from service on advisory committees or review panels for 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.
9. “University Official” for the purposes of this policy means the Radford University Vice President for Academic Affairs and University Provost, or his/her designee.



3. Policy

All Radford University faculty members must ensure they are conducting research in accordance with the highest standards of professionalism, integrity, and ethics. These standards also include reporting any significant financial interest that could pose a conflict of interest in their sponsored research.

An individual conflict of interest arises when a faculty member is in a position to advance one's own interests, or that of one's family or others, to the detriment of the university and/or the sponsored project. A conflict of interest is identified and assessed based on the factual context of the situation and is not based on any implied judgment about the character or intent of the individual.

State law and federal regulations define *significant financial interest* differently and the conditions under which a conflict of interest may be permitted. The Virginia State and Local Government Conflict of Interest Act defines a prohibited conflict of interest when an employee, or a company in which an employee or member of the employee's immediate family, has a personal interest contract directly or through a subcontract with a state institution of higher education. A *significant financial interest* is defined as owning three percent or more of the equity in the company or receiving payments from the entity of \$10,000 or more annually from consulting fees, salary, royalties, honoraria, rent or other income.

In the case of grants and contracts, federal agency guidelines on conflict of interest disclosure apply in addition to the state requirements. Consequently, all investigators, whether primary or co-primary, are required to disclose *significant financial interest* beyond that required by state law to comply with federal regulations. For PUBLICLY TRADED COMPANIES, a significant financial interest exists if the value of any remuneration received from that particular entity in the past twelve months preceding the disclosure and the value of the equity interest in said entity as of the date of the disclosure, when aggregate, exceeds \$5,000. For NON-PUBLIC COMPANIES, the threshold is \$5,000 for remuneration or when the investigator or investigator's spouse or immediate family members hold an equity interest (e.g., stock, stock option, or other form of ownership interest). PLEASE SEE THE DEFINITION SECTION OF THIS POLICY FOR MORE DETAILED DEFINITION OF *SIGNIFICANT FINANCIAL INTEREST*, AS WELL AS INCOME OR INVESTMENTS EXCLUDED FROM THIS POLICY.

The required disclosures of significant financial interest are those that relate to the investigator's university responsibilities. University responsibilities are defined broadly and include but are not limited to teaching, advising, research and scholarly activities, outreach, administrative and institution committee assignments, and service to professional associations.



3.1 Potential Conflict of Interest Involving Sponsored Research

To ensure compliance with federal regulations, and to provide consistent treatment of this policy for all research sponsors, all investigators engaged in sponsored research must disclose any significant financial interest, as defined by this policy, to the Office of Sponsored Programs and Grants Management. The investigator must clearly present in full detail his or her significant financial interests. The investigator's obligation to disclose extends to all collaborators, consultants, and subcontractors on a sponsored project, who must certify disclosure and compliance with conflict of interest policies promulgated by their home institution or, in absence of relevant institutional policies, must disclose directly to Radford University.

3.2 Disclosure Requirement

Both state law and federal regulations require that faculty members fully disclose *significant financial interests* that present a potential conflict with one's university responsibilities. All investigators, or their immediate family members, who own or have ownership interest in a private business that would appear to be related to their university responsibilities must disclose the significant financial interest and have it evaluated by the University to determine if any conflict of interest exists. Radford University will follow regulations as set forth in the Code of Federal Regulations and state law to respond to a written request for information concerning projects funded by the Public Health Service.

3.3 Annual Certification Requirement

All investigators supported by federal grants or contracts will certify annually, for as long as the award remains active, to a change in status, if any, from their initial *significant financial interest disclosure* that was submitted to the Office of Sponsored Programs and Grants Management prior to proposal submission.

3.4 Training Requirement

Due to the complex nature and importance of identifying and managing conflicts of interest, initial and periodic training concerning this policy, state law, and federal regulation is required for all faculty engaged in federally sponsored research. Federal regulations require investigators to complete training prior to the award of a grant or contract, as well as, at minimum every four years.



Immediate training or retraining is required for federally supported investigators if the University revises this policy at any time, if an investigator is new to the University, or if an investigator is not in compliance with this policy. Policy guidance will be provided by either the Research Compliance Office or the Office of Sponsored Programs and Grants Management.

4. Procedures

4.1 Disclosure of Potential Conflict of Interest

The Disclosure of Significant Financial Interest Form is used to disclose any external activities, or relationships with external activities, that may involve a potential conflict of interest. Examples of activities that require full disclosure are available on the Conflict of Interest website managed by the Research Compliance Office. Disclosure forms, where applicable, must be filed and approved prior to submission of a related proposal for sponsored research.

For investigators who are supported by federal funding, reimbursed, or sponsored travel paid for by an external entity must also be disclosed. At minimum, the disclosure of such travel will contain: the reason for the trip, identity of the organizer, the destination, and the duration. Disclosures NOT required are for travel reimbursed by the university from any university funding source (e.g., Research Support Account, E&G, Sponsored Project, Foundation), or travel paid for (or reimbursed) by a federal, state, or local government agency, or an institution of higher education or academic teaching hospital.

It is very important for faculty to describe in detail the relationship with external entities, including but not limited to the extent of personal or immediate family financial interests, any involvement of students or other employees, and any project-specific considerations. Disclosures will be submitted to the Office of Sponsored Programs and Grants Management for initial review and processing and then forwarded to the Research Compliance Office in care of the University Official for final action.

A fully approved disclosure form and management plan, if relevant, must be in place and received by the Office of Sponsored Programs and Grants Management prior to the execution of a related grant or contract. An investigator's significant financial interest related to his or her sponsored project and key elements of the management plan are reported by the Office of Sponsored Programs and Grants Management to the federal awarding agency in accordance with those agency's requirements.

In the event that a significant financial interest is identified after a project has been established, the University Official will promptly review the disclosure and its relationship to the project and implement management plan to mitigate the potential conflict, to possibly include suspending further project activity pending a more complete review and determination of appropriate action.



Any such action taken by the university will be reported to the sponsor in accordance with the agency's guidelines, or for Public Health Service grants within 60 days of disclosure.

4.2 Management of Conflict of Interest

The management plan is used to document the strategies taken by the University and Investigator for eliminating, mitigating, or managing a potential conflict of interest. An approved management plan will reflect the commitment of the faculty member to the University through his or her adherence to the highest standards of professional ethics and conduct of research. The management plan will be specific to the sponsored project and will fully describe the situation giving rise to the potential conflict, the proposed strategy to eliminate, mitigate, or management the conflict, and the process by which the activities outlined in the management plan will be monitored. Appropriate monitoring shall include oversight that can evaluate the effectiveness of the plan while ensuring compliance. For Public Health Service regulations, disclosure of an investigator's significant financial interest must be made directly to the human subjects involved and in other public presentations as required in current regulations for Public Health Service funded research.

A Radford University faculty member may not serve as Principal Investigator, or Project Director, on a sponsored project that is funded by an external organization in which the faculty, or spouse or dependent children, has a significant financial interest. The Co-Investigator must be a faculty member who is not in a subordinate position to the faculty member who has a significant financial interest in the external organization. An oversight plan must be carefully created for those cases where the faculty member with the significant financial interest remains involved in the sponsored research. Faculty consulting with an external entity which then sponsors research at the University involving that faculty member also presents a conflict of interest which must either be eliminated or carefully managed.

All management plans are submitted to the Office of Sponsored Programs and Grants Management and then reviewed and approved by the Research Compliance Office /University Official.

Sponsored funding will be contingent upon acceptance and implementation of the plan by the Investigator. The Principal Investigator, or Project Director, is responsible for carrying out the management plan and ensuring compliance with federal regulations. The Principal Investigator, or Project Director, must submit a certification annually to the Office of Sponsored Programs and Grants Management and at the end of the sponsored project that demonstrates compliance with all conditions identified in the approved management plan. Such reports may also be required for submission to the federal agency funding the research.



5. Compliance

This policy is derived from regulations mandated by the Commonwealth of Virginia and Federal government. Radford University requires all faculty who submit and receive federally funded grants to comply with this policy. The Research Compliance Office and Office of Sponsored Programs and Grants Management are responsible for overseeing the implementation of this policy and associated procedures. The University Official, or his or her designee, will work cooperatively with Investigators and others to resolve any minor issues of non-compliance.

However, breaches of the disclosure process, including (a.) failures to comply with this process, whether by virtue of an employee's refusal to respond or by responding with incomplete or knowingly inaccurate information, (b.) failures to remedy conflicts, and (c.) failure to comply with an approved management plan, will be forwarded to the Office of Academic Affairs for investigation and immediate action. Instances of deliberate breach of this policy will be adjudicated in accordance with the applicable disciplinary policies and procedures as set forth in the applicable University Faculty Handbook(s). The University Official, or his or her designee, will be responsible for reporting an FCOI to PHS sponsors and as deemed applicable by the Office of Sponsored Programs and Grants Management, to other federal agencies and sponsoring entities.

6. Additional Compliance Requirements of the Federal Regulations

During an ongoing PHS research project, whenever an Investigator who is new to participating in the research project or an existing Investigator discloses a new financial interest to the institution, the financial interest will be reviewed within 60 days by the designated institutional official to determine whether an FCOI exists and, if so, a management plan will be implemented on at least on interim basis.

For PHS funded research, the designated University official must report an FCOI to the PHS funding agency: 1) prior to Radford's initial expenditure of funds, 2) within 60 days of identifying an FCOI for an added Investigator or a new FCOI for an existing Investigator, and 3) as an annual progress report or at the time of extension. If Radford University is the prime awardee of PHS funds, the designated institutional official is required to report the FCOI of collaborating Investigators from subrecipient institutions to PHS. The designated University official is also required to submit FCOI reports of Radford University Investigators to the awarded institution if Radford University is a subrecipient. SPGM is required to verify, by way of a written agreement with subrecipient institutions on PHS, NSF, or other relevant funded research, whether this policy in its entirety or the FCOI policy of the subrecipient institution will apply to its Investigators who are collaborating with Radford University Investigators.



As a rule, Radford University will require subrecipient institutions to maintain and administer their own FCOI policies and will only in exceptional circumstances assume primary responsibility for directly soliciting and reviewing subrecipient disclosures to make an FCOI determination. If the subrecipient institution uses this policy, the subrecipient will enter into a written agreement requiring its Investigators to report financial interests to Radford University and complete the university's COI training pursuant to this policy and associated procedures. Only the financial interests related to the subrecipient Investigators' responsibilities on the project must be disclosed to Radford University as per PHS regulations, under certain criteria, the designated institutional official will make available required information about an FCOI held by an Investigator on PHS-funded research to a requestor within 5 business days of a request. When the designated University official identifies a financial interest that was not disclosed, identified, reviewed, or managed in a timely manner, the official will review and make the determination of an FCOI and report the FCOI, if it exists, to PHS within 60 days. If an FCOI exists, the official will implement, on at least an interim basis, a management plan specifying the actions that have been, and will be, taken to manage the FCOI going forward.

Radford University will complete and document a retrospective review within 120 days of the non-compliance determination to determine whether any PHS or DOE-funded research conducted during the time-period of the non-compliance was biased in the design, conduct, or reporting of such research. The designated University official will enlist an independent individual to assist in making this assessment. If bias is found, the PHS awarding component will be notified promptly and a mitigation report will be submitted by the university. If applicable, the official will update the previously submitted FCOI report to specify the actions that the university and the Investigator will take to manage the FCOI going forward.

7. Records Retention

All original signed disclosure forms, management plans, and sponsor reports related to conflicts of interest on sponsored projects will be retained in the Research Compliance Office for official business use only in accordance university record retention guidelines.

8. References

Code of Federal Regulations, 42 CFR Chapter 1, Subchapter D, Part 50
Code of Virginia, State and Local Government Conflict of Interest Act
Radford University Teaching/Research Faculty Handbook
Radford University Administrative/Professional Faculty Handbook



9. Revision History:

Revision	Summary of Revisions	Revision Date
1.0	Revised to include reporting requirement to PHS agencies and other relevant funding agencies. Revised to include additional requirements mandated by federal regulations.	16-August-2023