

## **Procedures for Evaluating and Managing Potential Financial Conflicts of Interest**

All references to “the College” within these procedures refer to Randolph College in Lynchburg, VA. All references to college documents within these procedures refer to the policies and documents of Randolph College in Lynchburg, VA.

These procedures pertain to the Financial Disclosure Policy. All Investigators are required to either disclaim or disclose to the Vice President for Academic Affairs (VPAA) all Significant Financial Interests (SFI) of the Investigator and/or the Investigator’s spouse, partner, and dependent children. Investigators are personnel responsible for the design, conduct, or reporting of research under the terms of a federal grant or contract.

### **Review Criteria**

Review criteria include: a) the research activities of an Investigator, b) whether an Investigator’s activity is on-going or has ended, c) the level of the financial interest associated with an Investigator’s activity.

#### *Research Activities*

The Financial Conflict of Interest (FCOI) policies and procedures apply if the Investigator’s position at the College would allow the individual to affect the design, conduct, or reporting of a federally-funded project.

#### *Level of Financial Interest*

Significant Financial Interest (SFI) is defined in the Financial Disclosure Policy. Financial thresholds also apply to the individual’s spouse or domestic partner, and his or her dependent children. Any combination of remuneration or ownership that exceeds \$5,000 meets the threshold for an SFI.

1. Compensation of \$5,000 or more in a calendar year.
2. An ownership interest in a publicly-traded company valued at \$5,000 that is not held in a mutual fund or retirement account.
3. Any ownership interest in a privately-held company.
4. Any leadership position in a company.
5. Any travel expense sponsored or reimbursed by a company or entity not excluded in the Financial Disclosure Policy.
6. Any business relationship or contract that might benefit the individual in the course of the research.

#### *Timing*

Financial Disclosure Forms will be filed before a proposal to a federal-funder is submitted and at least annually if an Investigator has an active federal grant. The completed form will be reviewed by the Vice President for Academic Affairs (VPAA) for potential FCOIs as they are submitted.

SFIs that are determined by the VPAA to be FCOIs will be reported to the sponsoring agency in accordance with its requirements within 60 days of the determination. Projects that are completed will also be reviewed if analysis and reporting of results are still underway, and records on SFIs and FCOIs will be kept for three (3) years following the submission of the final expenditure report to the sponsoring agency, or until the resolution of any federal action involving those records, whichever is longer. Records will be maintained in a secured cabinet in the Sponsored Programs Office. Should SFIs arise while a project is already underway, it is the responsibility of the Investigator involved to inform the VPAA of the potential conflict within 30 days.

### **Procedures for Determining Conflict of Interest**

The VPAA shall review each disclosed SFI; determine whether that SFI relates to federally-funded research, and, if so, determine whether a FCOI exists; and determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce, or eliminate such conflict of interest. The VPAA may, depending on the scope and/or magnitude of the potential conflict, request that additional staff or faculty serve on an ad hoc Review Committee to assist in its timely review. Staff members who serve on the Review Committee will be those with professional obligations to keep confidences and who have routine access to the confidential treatment of sensitive information.

The following questions will guide the determination of FCOI, although additional questions may arise depending on the nature of the relationship between the individual in question and the outside entity.

- Would the individual in question risk a financial loss depending on the outcome of the research?
- Are there potential financial gains to the individual in question based on the outcome of the research?
- If the entity in question or the individual's relationship with that entity stands to benefit directly from the research as a vendor, subrecipient or otherwise interested party, is there a compelling scientific or technical reason for such a relationship?
  - If not, would there be cause for a reasonable person to question the Investigator's ability to be objective in conducting and reporting the research?

The Sponsored Programs Officer will maintain records of FCOI determination proceedings consistent with funding agency requirements, and the VPAA will provide access to agency representatives upon request. Such records may include but are not limited to: agenda and minutes of the Review Committee meetings; records of electronic communication between VPAA, Committee members and the Investigator; notes of verbal communications between VPAA, Committee and Investigator. Such records must provide information on the basis for determination of the presence or absence of a FCOI and the rationale for any resulting management plans.

*No Management Financial Interests*

Some outside activities meet the criteria for review, but the VPAA and/or Review Committee may determine that these activities do not require management and assign them to “no management” status. Either the VPAA or the Review Committee may assign activities to “no management” status. Such activities include:

1. Compensation from or ownership in a company that does not sell products or services (or is not working towards selling products or services) and does not fund research (e.g. hospitals, law firms, insurance companies, etc.)
2. Compensation for other employment (self or spouse) as long as there are no connections between the research and the other position
3. Compensation for consulting or other activities from a government agency or another university
4. Compensation from a professional society
5. Compensation to a spouse for speaking or consulting, even if the spouse is employed in the same field
6. Royalties managed by other universities
7. Ownership interests in academic publications
8. Leadership positions when the individual and his or her immediate family: a) do not receive compensation, b) do not hold an ownership interest, and c) have no other participation with the business entity (e.g. consulting, serving on a scientific advisory board, receiving funds for research)

*Financial Thresholds*

The VPAA monitors Investigator-reported outside activities meeting the criteria for review, and which do not fall into one of the “no management” types, to a management level based on financial thresholds.

For Investigators whose outside activity includes a combination of compensation, ownership, and leadership, the management level is determined for each type of financial interest and the highest level is given to the relationship. Any combination of interests that meets or exceeds the \$5,000 threshold is reviewed. For example, an Investigator receiving \$4,000 for consulting and holding stock valued at \$3,000 with one publicly-traded company would receive a full management plan for the relationship with that company.

The VPAA may assign “limited management” status to activities meeting the indicated criteria.

<b>Activity</b>	<b>No Review</b>	<b>No Management</b>	<b>Full Management</b>
<b>Compensation</b>	<\$5,000/year in combination with ownership	See “No management financial interests.”	>\$5,000
<b>Ownership interest in a publicly-traded company</b>	<\$5,000 in combination with compensation	See “No management financial interests.”	>\$5,000

<b>Activity</b>	<b>No Review</b>	<b>No Management</b>	<b>Full Management</b>
<b>Ownership interest in a privately-held company</b>	No ownership interest	See “No management financial interests.”	All ownership interests with potential financial gain/loss and relevance to research
<b>Leadership position<sup>1</sup></b>	No leadership position	Leadership positions without financial interests	All leadership positions with potential financial gain/loss and relevance to research
<b>Sponsored or Reimbursed Travel</b>	No travel	<\$5,000 in combination with other interests, or no scientific or technical relevance to research	High cost travel, travel in combination with other financial interests, and entity business interests relevant to research

<sup>1</sup>Leadership positions are defined as positions with fiduciary responsibility, including senior managers (presidents, vice presidents, etc.) and members of boards of directors. Scientific advisory board membership is not a leadership position.

## **Management Plans**

If the VPAA or the Review Committee determines that the Investigator has a FCOI, the VPAA will convene a Financial Conflict of Interest Committee (FCOI Committee). The FCOI Committee will review the research, the financial interests in question, and the areas of conflict, and devise a management plan with a combination of elements it deems most conducive to the continued objective pursuit of research. Conditions or restrictions that might be imposed to manage, reduce, or eliminate FCOIs may include but are not limited to: a) monitoring of research by independent reviewers; b) modification of the research plan; c) disqualification from participation in the portion of the federally-funded research that would be affected by SFIs; d) divestiture of SFIs; e) severance of relationships that create conflicts; or f) public disclosure of FCOIs. The Investigator will be consulted as to the implementation of the management plan; the Investigator must agree to the plan before the research can proceed. If the FCOI Committee and the Investigator cannot agree upon a management plan, the relevant regulatory bodies and funding agencies will be notified.

In cases where research is already underway, and a potential conflict emerges, the research will be suspended until either: a) the VPAA determines that no conflict is present, or b) the FCOI Committee and the Investigator agree upon a management plan.

The above steps (FCOI determination and formulation of management plans) will be completed and reported to the relevant funding agency/ies by the VPAA within 60 days of the determination of the SFI in question. Updates will be submitted to funding agencies annually in

compliance with relevant regulations. Additional reports may be provided upon request to the Audit Subcommittee of the Randolph College Board of Trustees for oversight purposes.

### **Enforcement Mechanisms**

Randolph College is committed to ensuring the integrity of research and the avoidance, elimination and/or management of conflicts of interest.

The following acts and failures violate the Financial Disclosure Policy:

1. Intentionally reporting incomplete, misleading or erroneous information on a disclosure form;
2. Failing to make a required disclosure of a known SFI;
3. Failure to provide information related to financial disclosures or an investigation of FCOI;
4. Failure to abide by the terms of a management plan;
5. Unreasonable delay in making a required disclosure of a known SFI.

A violation of this regulation is grounds for the discipline of an Investigator or other employee. Sanctions that may be imposed for such a violation include but are not limited to any one or more of the following:

1. Letter of admonition;
2. Temporary suspension of access to active research funding, either for a fixed term or pending completion of a remediation plan;
3. Temporary suspension of rights to apply for internal and external research funding as a Principal Investigator, either for a fixed term or pending completion of re-training and remediation;
4. Investigation and mitigation of possible bias in research resulting from improperly disclosed FCOIs, and reporting (within 120 days of discovery of the violation) of corrective action to the relevant funding agency/ies;
5. Inquiry into possible research misconduct as per the Research Misconduct Policy located on the College portal under Faculty/Faculty Development/Research Misconduct Policy.
6. Non-renewal of appointment, as per the terms and procedures outlined in the Faculty Handbook;
7. Involuntary termination of employment, as per the terms and procedures outlined in the Faculty Handbook.

Disciplinary proceedings initiated under this regulation shall be conducted in accordance with the *Faculty Handbook*, the *Employee Handbook*, and the *Student Handbook*, as applicable. All relevant regulatory bodies and funding agencies will be promptly informed of disciplinary sanctions.