



RIVANNA

Financial conflict of interest policy and procedure

FCOI POLICY AND PROCEDURE

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1. PURPOSE

This policy establishes RIVANNA's financial policy and procedures for the purpose of complying with state and federal regulations including Health and Human Services (HHS). The policy and procedures aim to comply with 42 CFR Part 50, Subpart F and 45 CFR 94.

2. SCOPE

The scope of this procedure pertains to all research investigators at RIVANNA and other personnel responsible for reporting financial conflict of interest (FCOI).

3. REFERENCED DOCUMENTS

- 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought."
- Final rule on 45 CFR 94, "Responsible Prospective Contractors" (<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>)
- NIH Grant Policy Statement (<https://grants.nih.gov/policy/nihgps/index.htm>)
- UVA example policy (<https://uvapolicy.virginia.edu/policy/RES-005>)

4. DEFINITIONS

Definitions used in this policy and procedure are the same as provided in the applicable federal regulations but are also provided below for convenience.

Family:

Includes any spouse or dependent child.

Financial Conflict of Interest (FCOI):

A Significant Financial Interest (defined below) that could directly and significantly affect the design, conduct, or reporting of the investigator's research.

Institutional Responsibilities:

An investigator's professional responsibilities on behalf of the Company which may include, for example, activities such as research, research consultation, advisory or board memberships institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator:

The project director or principal investigator and any other person, regardless of title or position: (1) who is responsible for the design, conduct, or reporting of research or proposed research, which may include, for example, senior research staff, collaborators or consultants; and (2) whose research is supported by extramural funding (not internal funds or gifts).

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Management Plan:

For this policy, an action plan to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PHS Awarding Component:

The organizational unit of the Public Health service (PHS) within Health and Human Services (HHS) which funds the investigator's research.

Research:

A systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses both basic and applied research and includes all research meeting the definition of "research" in the Code of Federal Regulations, Section [45 CFR 46](#) and/or "clinical investigation" in the Code of Federal Regulations, Section 21_CFR_56. The term includes but is not limited to any such activity for which research funding is available from a Public Health Service (PHS) Awarding Component through a grant or cooperative agreement, whether authorized under the Public Health Services Act (42 U.S.C 6A) or other statutory authority, including but not limited to a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Significant Financial Interest:

For this policy:

1. A financial interest consisting of one or more of the following interests of the investigator and those of the investigator's immediate family (spouse, dependent children), that reasonably appears to be related to: (a) the investigator's Institutional Responsibilities if the research will be PHS-funded, or (b) the study sponsor or an entity that would have an interest in the work and/or the outcome of the research project if the research will not be PHS-funded.
 - a. With regard to any 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 combined with the value of any equity interest held in the 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 any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - b. With regard to any 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

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investigator or his immediate family member holds any equity interest (e.g., stock, stock option, or other ownership interest);

- c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. The term *significant financial interest* also includes any reimbursed or sponsored travel related to their institutional responsibilities, including travel paid on behalf of the investigator and not reimbursed to the investigator (so that the exact monetary value may not be readily available); except for travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, as defined at [20 U.S.C. 1001\(a\)](#), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education as defined at [20 U.S.C. 1001\(a\)](#).
3. The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by or on behalf of RIVANNA to the investigator, including intellectual property rights assigned to RIVANNA 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; and, income from seminars, lectures, or teaching engagements sponsored by, 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 affiliated with an institution of higher education

5. PROCEDURE

A financial conflict of interest exists under this policy when an investigator or member of his or her immediate family has a *significant financial interest* that could directly and significantly affect the design, conduct, or reporting of research. Such a conflict must be disclosed, appropriately managed and, if required, reported to the sponsor.

The specifics of financial interests and their relation to the proposed research activity may vary considerably. Therefore, it is not possible to guarantee that research may proceed under a management plan in any and all cases of financial conflict of interest. In extreme situations, such as the involvement of investigators with significant financial interests in experiments with human participants, there will be a rebuttable presumption that such activities may not proceed.

5.1. Investigator disclosure requirements

An investigator who is planning to participate in research must disclose to RIVANNA's Authorized Administrative Official with FCOI delegation (AO) the investigator's significant financial interests as defined above, no later than the time of application for external research funding or prior to initiating research, whichever occurs first.

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The AO shall receive investigators' disclosures of significant financial interests and review it to determine if financial interests are related to the investigator's research, i.e., could be affected by the research or is in an entity whose financial interest could be affected by the research. The AO shall forward those financial interests determined to be related to the AO and Research Conflict of Interests Committee for action as described below.

The Research Conflict of Interests Committee shall comprise the AO and RIVANNA's upper management team.

5.2. Responsibilities of the Conflict of Interest Committee

Upon receipt of FCOI disclosure, Research Conflict of Interests Committee, which shall:

1. receive and review disclosures of significant financial interests that the AO has determined are related to the investigator's research, to determine whether they could directly and significantly affect the design, conduct, or reporting of the research, creating a financial conflict of interest;
2. recommend to the AO management plans for significant financial interests related to research that create financial conflicts of interests; and
3. through the AO, implement and monitor compliance with management plans approved by the Institutional Official, and when required make reports of financial conflicts of interests to the research sponsor.

The Research Conflict of Interests Committee shall cooperate with the AO to implement policies and procedures for investigators' disclosure and review of significant financial interests, management of financial conflicts of interests, reporting of interests to research sponsors when required, and record maintenance.

5.3. FCOI management plans

Acceptable FCOI management plans adopted by the Research COI Committee may include:

- Public disclosure of FCOI (e.g., when presenting or publishing the research);
- Disclosure of FCOI directly to human subjects research participants;
- Monitoring of research by independent reviewer(s);
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of Significant Financial Interests (e.g., sale of an equity interest)
- Severance of relationships that create financial conflicts.

The following key elements must be addressed in the plan:

1. Role and principal duties of the conflicted Investigator in the research project;
2. Conditions of the management plan;
3. How the management plan is designed to safeguard objectivity in the research project;
4. Confirmation of the Investigator's agreement to the management plan;

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5. How the management plan will be monitored to ensure Investigator compliance; and
6. Other information as needed.

5.4. Reporting to NIH

Upon conclusion of Research COI Committee's responsibilities according to Section 5.2 above, the AO shall promptly report the FCOI to the applicable NIH awarding component through the submission of an initial and annual FCOI report using the eRA Commons FCOI Module.

The annual FCOI must be submitted to the NIH through the FCOI Module each year within a competitive segment or until the FCOI no longer exists.

5.5. Training

Each Investigator is required to complete training to this Policy prior to engaging in research and at least every four years, and immediately when any of the following apply:

- (1) This FCOI policy and procedure changes in any manner that affects the requirements of investigators;
- (2) An investigator is new to RIVANNA; or
- (3) RIVANNA determines that an investigator is not in compliance with this FCOI or FCOI management plan.

5.6. Research through subcontractors

If research will be carried out through a sub-recipient (e.g., a subcontractor or consortium member) and is funded by PHS, NSF or a sponsor who has adopted PHS or NSF financial conflict of interest requirements:

- (a) the sub-recipient shall certify in a written agreement that its research conflict of interests policy complies with the sponsor requirement, and that it will report any financial conflicts of interests of its investigators to RIVANNA by dates sufficient for timely reporting by RIVANNA to the sponsor; or
- (b) if it is unable to certify compliance, the sub-recipient shall enter into a written agreement requiring its investigators to report significant financial interests to RIVANNA and complete the RIVANNA's FCOI training pursuant to this policy and procedure.

5.7. Responding to the public

RIVANNA shall respond in writing within five business days to requests from the public for information about FCOI of senior/key personnel (the principal investigator or project director and any other person identified as senior/key in the PHS funding application or other reports to PHS) if such conflicts are related to PHS-funded research. The response will be made in writing, postmarked within five business days, and include the investigator's name, a description of the

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interest, and its dollar value range as required by the HHS regulations on Promoting Objectivity in Research.

The same approach will be taken when responding public requests for information about research funded by sponsors who have adopted PHS financial conflict of interest requirements.

5.8. Dissemination policy

This FCOI Policy and Procedure shall be made publicly available on RIVANNA's website.

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6. ATTACHMENTS

6.1. Document Change Information

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A	DCO-000837	01/01/2017	Will Mauldin	Initial release

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