FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

Research and Sponsored Programs

Purpose

The purpose of this Policy is to promote objectivity in research and comply with federal regulations governing Financial Conflicts of Interest (FCOI), including 42 CFR Part 50 Subpart F and other applicable sponsor requirements. This Policy establishes standards for identifying, disclosing, reviewing, managing, reducing, or eliminating financial conflicts of interest that may directly and significantly affect the design, conduct, or reporting of sponsored research.

Scope

This Policy applies to all Investigators who are planning to participate in, or are participating in, externally sponsored research administered by the University, including Public Health Service (PHS) and National Institutes of Health (NIH) funded research.

For purposes of this Policy, an Investigator is any individual, regardless of title or position, who is responsible for the design, conduct, or reporting of sponsored research, including Principal Investigators, Project Directors, Co-Investigators, and other key personnel.

Policy Statement

The University is committed to maintaining the highest standards of integrity, transparency, and objectivity in research. All Investigators must disclose Significant Financial Interests (SFIs) related to their institutional responsibilities. The University shall review all disclosed SFIs, determine whether Financial Conflicts of Interest exist, and manage identified conflicts in accordance with applicable regulations and sponsor requirements.

Definitions

Financial Conflict of Interest (FCOI)

A Financial Conflict of Interest exists when the University, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of sponsored research.

Significant Financial Interest (SFI)

A Significant Financial Interest includes foreign and domestic financial interests of an Investigator, the Investigator's spouse, and dependent children that reasonably appear related to the Investigator's institutional responsibilities, including but not limited to:

- Salary, consulting fees, honoraria, or other compensation;
- Equity interests in publicly traded or non-publicly traded entities;
- Intellectual property rights and interests upon receipt of income;
- Sponsored or reimbursed travel; and
- Other financial interests as defined by applicable federal regulations.

Excluded interests are those specifically exempted by applicable federal regulations.

Institutional Responsibilities

Institutional Responsibilities include an Investigator's professional activities on behalf of the University, including research, teaching, service, professional practice, institutional committee activities, and administrative responsibilities.

Training Requirements

The University shall inform Investigators of:

- This Policy;
- Their disclosure responsibilities; and
- Applicable federal conflict-of-interest regulations.

Each Investigator participating in NIH- or PHS-funded research shall complete FCOI training:

- Prior to engaging in sponsored research;
- At least once every four (4) years thereafter;
- Immediately when this Policy is substantively revised;
- When the Investigator is new to the University; or
- When the University determines that the Investigator is not in compliance with this Policy or an FCOI management plan.

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Disclosure Requirements

Each Investigator shall disclose all required Significant Financial Interests, including those of the Investigator's spouse and dependent children:

1. No later than the time of application for sponsored research funding;
2. At least annually during the period of an award;
3. Within thirty (30) days of discovering or acquiring a new Significant Financial Interest; and
4. Within thirty (30) days of each occurrence of sponsored or reimbursed travel, when required by applicable regulations.

Required travel disclosures shall include:

- Purpose of the trip;
- Identity of the sponsor or organizer;
- Destination; and
- Duration of travel.

Designated Institutional Official

The Director of Government Programs and Human Subjects Research shall serve as the Institutional Official responsible for administration of this Policy.

The Institutional Official shall:

- Solicit and review disclosures;
- Determine whether disclosed SFIs are related to sponsored research;
- Determine whether an FCOI exists;
- Develop and oversee management plans;
- Monitor compliance;
- Maintain required records; and
- Submit sponsor-required FCOI reports.

Review of Disclosures

Prior to the expenditure of project funds, the Institutional Official shall:

1. Review all disclosed SFIs;
2. Determine whether an SFI is related to sponsored research; and
3. Determine whether the SFI constitutes an FCOI.

An SFI is considered related to sponsored research when the Institutional Official reasonably determines that the SFI:

• Could be affected by the research; or
• Is held in an entity whose financial interests could be affected by the research.

Management of Financial Conflicts of Interest

Whenever an FCOI is identified, the University shall implement a written management plan before expenditure of funds whenever required.

Management strategies may include:

• Public disclosure of the conflict;
• Disclosure to human subjects;
• Independent monitoring of the research;
• Modification of the research plan;
• Modification of personnel responsibilities;
• Disqualification from participation in all or portions of the project;
• Reduction or elimination of the financial interest; or
• Severance of relationships creating the conflict.

The University shall monitor Investigator compliance with management plans throughout the life of the project.

New Investigators and Newly Disclosed Interests

When:

• A new Investigator joins an ongoing project; or
• An Investigator discloses a new Significant Financial Interest,

the Institutional Official shall, within sixty (60) days:

• Review the disclosure;
• Determine whether the SFI is related to the sponsored research;
• Determine whether an FCOI exists; and
• Implement an interim or final management plan, as appropriate.

Noncompliance and Retrospective Review

If an SFI was not disclosed in a timely manner, was not reviewed, or an FCOI was not appropriately managed, the University shall:

• Complete a review within sixty (60) days of discovery;
• Implement an interim management plan as necessary; and

• Conduct a retrospective review within one hundred and twenty (120) days when required by regulation.

The retrospective review shall document:

• Project number and title;
• Principal Investigator;
• Investigator with the conflict;
• Entity involved;
• Reasons for the review;
• Methodology used;
• Findings; and
• Conclusions.

If bias is identified, the University shall promptly submit any required mitigation report to the sponsor and implement corrective actions.

Reporting Requirements

For NIH/PHS-funded research and other sponsored projects requiring conflict-of-interest reporting, the University shall submit FCOI reports:

• Prior to expenditure of funds, when required;
• Within sixty (60) days of identifying a new FCOI;
• Annually for ongoing projects; and
• Following retrospective reviews when updated information must be reported.

The University shall promptly notify sponsors when required by law, regulation, or award terms.

Subrecipient Requirements

When sponsored research involves a subrecipient, the University shall establish a written agreement specifying whether the University's FCOI policy or the subrecipient's policy will apply.

If the subrecipient's policy applies, the subrecipient must certify that its policy complies with applicable federal regulations.

The agreement shall require timely reporting of identified FCOIs sufficient to allow the University to meet all sponsor reporting obligations.

Public Accessibility

The University shall:

• Make this Policy publicly accessible on its website; and
• Make information regarding certain identified FCOIs of senior/key personnel publicly available as required by federal regulation.

Required public information shall:

• Be updated at least annually;
• Be updated within sixty (60) days of newly identified FCOIs; and
• Remain publicly available for at least three (3) years from the date of the most recent update.

Record Retention

The University shall maintain all records relating to:

• Investigator disclosures;
• Reviews and determinations;
• Management plans;
• Training records;
• FCOI reports;
• Retrospective reviews; and
• Other actions under this Policy.

Records shall be retained for at least three (3) years from submission of the final expenditure report or for longer periods when required by applicable regulations.

Enforcement and Sanctions

Failure to comply with this Policy may result in:
• Mandatory retraining;
• Corrective action plans;
• Suspension of research activities;
• Restrictions on proposal submission;
• Removal from a project; or
• Other disciplinary or administrative action consistent with university policies.

Responsibilities

Investigators

• Complete required training;
• Submit complete and timely disclosures;
• Comply with management plans; and
• Cooperate with reviews and monitoring activities.

Institutional Official

• Administer the FCOI program;
• Review disclosures;
• Determine FCOIs;
• Develop and monitor management plans;
• Submit sponsor reports;
• Maintain records; and
• Ensure compliance with applicable regulations.

Effective Date and Review

This Policy shall become effective upon approval and shall be reviewed periodically to ensure compliance with evolving federal regulations and sponsor requirements. This Policy supersedes prior research-related financial conflict of interest policies and procedures governing sponsored research but is intended to supplement, and not replace, other University conflict of interest policies. Investigators and other University personnel remain subject to all applicable non-research conflict of interest disclosure and compliance requirements.