

# Oklahoma State University Policy and Procedures

## CONFLICT OF INTEREST IN SPONSORED PROGRAMS

4-0130  
RESEARCH  
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### INTRODUCTION

1.01 As an institution dedicated to excellence in education, research and extension/outreach, Oklahoma State University (OSU) places a high value on research integrity and academic freedom. Objectivity in the conduct of research, the freedom to disseminate ideas through publication of research results, the protection of the rights and interests of research participants, maintenance of public trust, and the ability to ensure that our responsibility to our students and trainees is not compromised are critical to these institutional values. Relationships with industry and other outside entities, while important to the support and advancement of research, can present special challenges in protecting these institutional values.

1.02 The purpose of this policy is to ensure objectivity in research.

1.03 This policy was developed in accordance with regulations found in 2 C.F.R. § 200, and grant policies of the U.S. Public Health Service (PHS) and its constituent agencies, including the National Institutes of Health (NIH) and the Food and Drug Administration (FDA), the National Science Foundation (NSF), and the U.S. Department of Education. All OSU Investigators who apply for or receive funding from any sponsor for a research project will comply with the requirements of this policy and applicable OSU conflict of interest procedures for PHS funded research or non-PHS funded research. Additional requirements may also be applicable, depending upon the sponsor's grant/contract terms.

1.04 It is the intent of this policy to provide assurance to investigators, OSU, sponsors of institutional research, and the public, that research activities at OSU will be conducted in a manner consistent with institutional and public values.

1.05 This policy applies to all OSU personnel at OSU Stillwater and OSU Tulsa, including but not limited to, administrators, faculty, staff, post-doctoral fellows, and students with responsibility for the design, conduct, or reporting of research, either funded or proposed for funding.

### DEFINITIONS

These definitions apply to terms as they are used in this policy.

2.01 **Conflict Management** - Measures taken to address the risk of bias or the appearance of bias, protect research subjects, and maintain public trust in the institution's research and its personnel when research personnel may have a real or apparent Financial Conflict of Interest (FCOI). Conflict Management may be set forth in a conflict of interest management plan (Management Plan).

2.02 **Design, Conduct or Reporting of Research** - Oversight, decision-making, or participation in research that includes creating the structure, roles, and/or protocol of a research project; participating in the execution of the research roles and protocol; participating in the publishing, presentation, or discussion of research results.

2.03 **Disclose/Disclosure** - To provide relevant, complete, and timely information about financial interests related to a research project to parties internal or external to the institution to ensure full awareness of potential conflicts and institutional efforts to address them.

2.04 **Financial Conflict of Interest (FCOI)** - A Financial Conflict of Interest occurs when a financial interest, or other opportunity for personal financial gain, could significantly and directly compromise or influence the objective design, conduct, reporting, or direct administration of research.

2.05 **Financial Threshold** - For personnel on PHS funded awards or cooperative agreements, the threshold for reporting a Significant Financial Interest (defined below) is U.S. \$5,000, as per PHS requirements. For NSF supported research, the threshold for reporting a Significant Financial Interest is U.S. \$10,000. Some agencies and sponsors require Disclosure of all sponsored travel, as well as Disclosure of equity in non-publicly traded companies, regardless of the dollar value (*see* Sections 2.8(4) and 2.9 below).

2.06 **Investigator(s)** - *Investigator* means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded, or proposed for such funding, which may include, for example, collaborators or consultants.

2.07 **Management Plan** - *See Conflict Management (Section 2.01).*

2.08 **Significant Financial Interest (SFI)** - A financial interest consisting of one or more of an individual's interests (or the interests of a spouse or dependent child) that reasonably appears to be related to an individual's Oklahoma State University responsibilities. SFI includes the following types of financial interests:

- A. With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve (12) months preceding the Disclosure and the value of any equity interest in the entity as of the date of Disclosure, when aggregated, exceeds the Financial Threshold. For the purpose of an SFI, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship) and equity interests include 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, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds the Financial Threshold, or when an individual or his or her family holds any equity interest (e.g., stock, stock option, or other ownership interest).

- C. With regard to intellectual property rights and interests (e.g., patents, copyrights), an SFI exists upon receipt of income related to such rights and interests.
- D. With regard to travel for personnel on PHS funded awards or cooperative agreements, an SFI exists if any travel that is reimbursed or paid on the individual's behalf is related to the individual's OSU responsibilities. This excludes any travel that is reimbursed or sponsored by OSU, a federal, state, or local government agency, a U.S. non-profit institution of higher education as defined at 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. institution of higher education.

**SFI does not include** the following types of financial interests:

- A. Salaries, royalties, and other remuneration paid by OSU or the Oklahoma State University Research Foundation (OSURF) to an individual, including commercialization revenue stemming from University Intellectual Property pursuant to OSU Policy 1-0202, and income from intellectual property rights assigned to the institution and agreements to share in royalties related to such rights.
- B. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the individual does not directly control investment decisions made in these vehicles.
- C. Income from seminars, lectures, teaching engagements, and service on advisory committees or review panels, when such income is paid by government agencies, U.S. institutions of higher education, or by an academic teaching hospital, medical center, or research institute that is affiliated with a U.S. institution of higher education.

**2.09 Travel Disclosure** - Some agencies, including PHS, require Disclosure of all reimbursed or sponsored travel related to an Investigator's institutional responsibilities within thirty (30) days of completing travel.

**Sponsored Travel** means (a) travel expenses paid to an Investigator or travel paid on an Investigator's behalf in the past 12-month period, and (b) travel reimbursed to or paid on behalf of an Investigator's spouse or dependent child by a single entity in any twelve (12) month period **ONLY** if such travel reasonably appears to be related to the Investigator's OSU responsibilities. This Disclosure requirement does not apply to travel that is reimbursed or sponsored by OSU, a federal, state, or local government agency, a U.S. non-profit institution of higher education as defined at 20 U.S.C. § 1001(a), or by an academic teaching hospital, medical center, or research institute that is affiliated with a U.S. institution of higher education. The details of this Disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

## **POLICY AND PROCEDURES**

No proposed, awarded, or ongoing research project at the University shall be biased by a Financial Conflict of Interest of any Investigator responsible for the design, conduct or reporting of the research. The University and Investigators have a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest of an Investigator.

3.01 Responsibilities of Investigators. In addition to other responsibilities as specified in this policy, Investigators shall be responsible for:

- A. Timely and accurate Disclosure of SFIs of the Investigator, spouse and dependent children. For PHS/NSF supported research, Disclosure is required prior to proposal submission and at least annually during the period of award. Updates to Disclosures must be submitted within 30 days of discovering or acquiring a new SFI;
- B. Completion of training as required by applicable regulation and funding agency and sponsor policies. PHS requires training prior to engagement in PHS-funded work, at least every 4 years and immediately when certain revisions to policy are made, when an Investigator changes institutions, and when an Investigator is found to be out of compliance with this policy;
- C. Ensuring that co-investigators, staff, students, contractors, sub-recipients, and other individuals responsible for the design, conduct, or reporting of the Investigator's research comply with the requirements of this policy;
- D. Collaborating with departmental, college-level, and University administration to develop timely conflict of interest Management Plans (if required), and implementing and ensuring compliance with those plans;
- E. Reading and understanding this policy and cooperating with the Office of the Vice President for Research to ensure compliance with the requirements set forth in this policy, corresponding procedures, and applicable regulation.

3.02 Management of Financial Conflicts of Interest. The Research Conflict of Interest Officer (RCIO) will be appointed by the Vice President for Research (VPR) to administer the Disclosure of Investigators SFIs under this policy and the related procedures. The RCIO, at her/his discretion, may refer a Disclosure of SFI to the Conflict of Interest Review Committee (a standing committee, described below) if the SFI has the potential to be categorized as an FCOI.

The VPR will appoint the members of a standing Conflict of Interest Review Committee, which will comprise at least three (3) members of the OSU faculty, staff, or administration with relevant background or expertise. At least one member of the Committee must be a tenured OSU faculty member selected by the VPR to serve as the Chair of the Committee.

The Committee will meet to review all Disclosures referred by the RCIO and determine if any referred SFI constitutes an FCOI and, if so, what modifications or conditions, if any, should be imposed to manage, reduce or eliminate the FCOI. During the course of its review, the Committee

may require the Investigator to submit more detailed information regarding the SFI and any related project proposed for funding or awarded and may require the Investigator to meet with the Committee.

The Committee will take one of the following actions on each Disclosure referred for review:

- A. Determine that an FCOI does NOT exist;
- B. Determine that an FCOI DOES exist; and
  - 1. Require modifications, conditions, or administrative oversight to reduce or eliminate or manage each conflict for the proposed project in a Management Plan;  
**OR**
  - 2. Require withdrawal of the proposed project.

Examples of conditions or restrictions that might be imposed by the Conflict of Interest Review Committee in a Management Plan 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 the 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 of 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); and/or
- G. Severance of relationships that create financial conflicts.

The Conflict of Interest Review Committee will notify the Investigator and the RCIO of the Committee's decision in writing. If the Investigator does not agree with any modifications or conditions imposed by the Committee or with the Committee's recommendation that the proposed project be withdrawn, the Investigator will have ten (10) business days following receipt of such notice to appeal the decision to the RCIO. The RCIO will then convene a panel to review the appeal and determine whether to recommend upholding the Committee's decision or to recommend an alternative decision to the VPR. The appeal panel will comprise at least two Deans (or the Deans' designees) selected by the RCIO and additional members may be added at the RCIO's discretion for complex cases. Following the appeal panel's review, the RCIO will communicate the Committee's original decision, the Investigator's appeal, and the appeal panel's recommendations to the VPR. Within ten (10) days of receipt of the appeal materials, the VPR will notify the Investigator, the Conflict of Interest Review Committee, and the RCIO of his/her decision in writing. The decision of the VPR will be final.

A copy of any conflict Management Plan adopted by the Conflict of Interest Review Committee or by the VPR (following an Investigator's appeal) will be maintained by the RCIO. The RCIO will make any necessary reports to funding agencies or non-agency sponsors in accordance with federal regulations or sponsor requirements.

Any conditions or restrictions to resolve or manage conflicts of interest under the Management Plan must be implemented before OSU's expenditure of any funds awarded under a grant or contract. The Conflict of Interest Review Committee will monitor Investigator compliance with any implemented Management Plan on an ongoing basis until the completion of the funded project.

3.03 Retrospective Review. If an Investigator fails to Disclose an SFI that the RCIO later determines to be an FCOI related to a particular research project, if the University fails to review or manage an FCOI, or if an Investigator fails to comply with the terms of a Management Plan, the University will within one hundred and twenty (120) days complete a retrospective review of the Investigator's research to determine whether there was any bias in the design, conduct or reporting of the research. The RCIO will keep a record of the retrospective review and make any necessary reports to funding agencies or non-agency sponsors in accordance with federal regulations or sponsor requirements.

3.04 Maintenance of Records. The RCIO will maintain records relating to all Investigator Disclosures of SFIs and OSU's actions in response to such disclosures until the later of: (1) at least three (3) years from the date the final expenditure report is submitted to the funding agency or non-agency sponsor, unless the funding agency or non-agency sponsor requires another retention period; (2) the resolution of any governmental action involving such records; (3) the date specified by federal or state laws or regulation (*see, e.g.*, 51 O.S. §§24A.1-24A.30; 45 C.F.R. §75.361); or (4) any applicable state or institutional records retention schedule.

3.05 Enforcement Mechanisms, Remedies and Noncompliance. The Office of the VPR shall monitor Investigators and Disclosures of conflicts of interest to determine compliance with this policy and related procedures. Failure to comply with this policy will be grounds for disciplinary action in accordance with OSU Policy Statement to Govern Appointments, Tenure, Promotions, and Related Matters of the Faculty of Oklahoma State University; OSU Policy 3-0720 (for staff), and the OSU Student Code of Conduct.

In addition, Investigators may also be subject to criminal sanctions or civil liability under federal or state law. Violations of full and prompt Disclosure may result in the loss of grant or contract funding and sanctions regarding future funding from federal agencies and non-agency sponsors. For PHS funded research, Investigators may also be subject to additional remedies as set out in the applicable Conflict of Interest procedure.

3.06 Compliance Reporting. Any suspected violation of this policy and related procedures must be reported to the RCIO, the University Research Compliance Office, or the VPR. Anonymous reports may be submitted to the RCIO at [RCIO@okstate.edu](mailto:RCIO@okstate.edu) or via the OSU/A&M EthicsPoint system.

## REFERENCES

2 C.F.R. § 200, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards*.

U.S. Public Health Service (PHS), 42 C.F.R. § 50 Subpart F (grants and cooperative agreements): “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought” [http://grants.nih.gov/grants/compliance/42\\_CFR\\_50\\_Subpart\\_F.htm](http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm)

National Science Foundation: NSF Proposal & Award Policies & Procedures Guide (PAPPG) (NSF 18-1 or the latest version), see Conflict of Interest Policies, Chapter IX. [https://www.nsf.gov/pubs/policydocs/pappg18\\_1/index.jsp](https://www.nsf.gov/pubs/policydocs/pappg18_1/index.jsp)

U.S. Department of Education: 34 C.F.R. § 75.524, 34 C.F.R. § 75.525 and 34 C.F.R. § 74.42.  
Food and Drug Administration regulated research: 21 C.F.R. § 54.

45 C.F.R. § 75.361, *Retention Requirements for Records*.

Approved:

Board of Regents, September 1996

Board of Regents, September 2012

Board of Regents, December 2020

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E-Team, August 2012 (Compliance date)

E-Team, November 2020