

LOUISIANA STATE UNIVERSITY AGRICULTURAL CENTER

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RESPONSIBLE OFFICE: Office of Sponsored Programs

CATEGORY: Administration

Disclosure of Significant Financial Interests to Prevent Bias in Research

Purpose:

The purpose of this policy is to establish guidelines covering the disclosure of financial interests and the management of financial conflicts of interest that could bias the outcome of sponsored projects involving the research, education, and service activities of LSU Agricultural Center (Institution) units.

Additionally, this policy promotes objectivity in research by establishing standards that comply with the policies of funding agencies including but not limited to the U.S. Department of Health and Human Services Public Health Services (PHS), the agencies that have adopted PHS requirements, the U.S. Department of Agriculture, and the National Science Foundation. Note that the training requirements and use of the online disclosure mechanism provided for in this policy will become effective when the GeauxGrants Conflict of Interest (COI) module is in place.

Scope:

This Policy applies to all individuals engaged in sponsored projects involving research, education, and service activities for the LSU Agricultural Center. For the purpose of the Policy, activities involving research, education and service will be deemed research.

This policy does not replace or supersede general institutional or LSU Administration policies governing disclosure of activities and financial interests relating to outside employment (PM-11/PS-26) or state employees contracting with the University (PM-67).

1. Definitions:

Conflict of Interest Committee (COI Committee) means the Institution's committee that advises the Institutional Official on Financial Conflict of Interest matters.

Entity means any domestic or foreign, public or private, organization (excluding a federal

agency) from which an Investigator or Investigator's Family receives remuneration or in which any person has an ownership or equity interest.

Family means any member of the Investigator's immediate family, specifically spouse or partner and dependent children.

Financial Conflict of Interest means a Significant Financial Interest that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of the research.

Institutional Official means the individual within the Institution who is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family related to the Investigator's institutional responsibilities.

Investigator means the project director, principal Investigator, co-investigator, and any other individual, regardless of title or position, who is responsible for the design, conduct, or reporting of research or applications/proposals for such research.

Investigator's Institutional Responsibilities means the Investigator's responsibilities associated with his or her Institutional appointment or position, such as research, research consultation, teaching, service activities, administration, internal professional committee service such as a committee membership in Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC), and external professional committee service.

Senior/key personnel means the principal investigator/project director and any other person identified as senior/key personnel by the Institution in the application/proposal, progress report, or any other report submitted to the funding agency.

Significant Financial Interest means a financial interest of the Investigator and their Family that reasonably appears to be related to the Investigator's Institutional Responsibilities, and is one or more of the following:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services (e.g. consulting fees, honoraria, paid authorship) received during the 12-month period preceding the disclosure, and the value of any equity interest (includes stock, stock option or other ownership interest) during the 12-month period preceding or as of the date of disclosure, exceeds \$5,000;
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services (e.g. consulting fees, honoraria, paid authorship) received during the 12-month period preceding the disclosure exceeds \$5,000;
- c) if with a non-publicly traded company, is an equity interest (includes stock, stock option or other ownership interest) of any value during the 12-month period preceding or as of the date of disclosure; or
- d) is income related to intellectual property rights and interests (e.g. patents, copyrights) not reimbursed through the Institution.

Significant Financial Interest also includes 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), related to their institutional responsibilities. This disclosure requirement does not apply to travel that is reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers. A Significant Financial Interest exists if the reimbursed or sponsored travel exceeds \$5,000 from a single entity during a 12-month period.

Significant Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from the Institution;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by a U.S. Federal, state or local governmental agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a U.S. research institute affiliated with an institution of higher education;
- d) income from service on advisory committees or review panels for a U.S. Federal, state or local governmental agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a U.S. research institute affiliated with an institution of higher education;
- e) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

2. Disclosure Requirements:

Determination of Significant Financial Interest is the individual obligation of the Investigator. If an Investigator determines that a Significant Financial Interest exists, they must disclose same in accordance with this Policy Statement. If an Investigator determines that a Significant Financial Interest does not exist, then there is no requirement to report the negative determination unless in response to direct inquiry, such as responding to questions on the Sponsored Programs Proposal Routing Form or the like.

Annual Disclosure

All Investigators must disclose the Significant Financial Interests that are related to the Investigator's Institutional Responsibilities to the Institutional Official on an annual basis. The due date for the annual disclosure is 12 months following their initial disclosure. New Investigators must disclose their Significant Financial Interest within 30 days of their employment with the LSU Agricultural Center.

Application/proposal Disclosure

All Investigators must confirm their annual disclosure is current or disclose additional Significant Financial Interest each time they submit an application/proposal for a sponsored project.

Ad hoc Disclosure

All Investigators must submit an updated Significant Financial Interest disclosure within 30 days of discovering or acquiring a new Significant Financial Interest.

Sponsor Required Disclosure

Disclosure shall be in accordance with sponsor requirements if the requirements are more restrictive than this policy.

3. Review, Determination and Management of Financial Conflict of Interest:

Review and Determination

The Institutional Official will review all Significant Financial Interest disclosures to determine whether an Investigator's Significant Financial Interest constitutes a Financial Conflict of Interest related to the Investigator's sponsored project. The Institutional Official may recommend to LSU Agricultural Center upper administration that a COI Committee be appointed. The COI Committee will be used for consultation and guidance in specific or complex cases, or the application of the policy to a particular situation. A Financial Conflict of Interest will exist when the Institutional Official determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the research.

Management

The Institutional Official, working with other designated officials as appropriate, will develop and implement a written management plan for all identified Financial Conflicts of Interest related to a sponsored project before any sponsored project funds are expended.

The management plan may impose any condition and prescribe any action necessary to manage a Financial Conflict of Interest, including an action reducing or eliminating the Financial Conflict of Interest, to ensure that the design, conduct, or reporting of the research is free from bias or the appearance of bias. Examples of conditions or actions that may be prescribed include, but are in no way limited to:

- a) public disclosure of the conflict of interest in presentations and publications;
- b) for human subjects research, direct disclosure of the conflict of interest to research participants;
- c) appointment of an independent monitor with authority to take measures to protect the design, conduct, and reporting of research against bias, or the appearance of bias, resulting from the conflict of interest;
- 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) divestiture or reduction of the financial interest; or
- g) severance of relationships that create an actual or potential Financial Conflict of Interest.

The management plan must be in the form of a written agreement and must provide that the Investigator acknowledges receipt of the approved plan and understands the requirements of

this Policy and the required actions and other terms of the plan.

If, during the course of an ongoing sponsored project, an Investigator new to the project discloses a Significant Financial Interest, or a new Significant Financial Interest is disclosed by an existing Investigator, the Institutional Official, working with other designated officials as appropriate, shall within 60 days review the disclosure, determine if the Significant Financial Interest represents a Financial Conflict of Interest for the sponsored project and if so implement, on at least an interim basis, a management plan as described above. Depending on the nature of the Significant Financial Interest, the Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the sponsored project.

Additionally, if during the course of an ongoing sponsored project, the Institution identifies a Significant Financial Interest that was not disclosed timely by an Investigator, or, for whatever reason, was not previously reviewed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), the Institutional Official, working with other designated officials as appropriate, shall within 60 days review the disclosure, determine if the Significant Financial Interest represents a Financial Conflict of Interest for the sponsored project and if so implement, on at least an interim basis, a management plan as described above.

4. Reporting:

If a funding agency requires that the Institution report sponsored project-related Financial Conflicts of Interest, the Office of Sponsored Programs will submit the report on behalf of the Institution's Authorized Representative. The report content, type of submission and timing will be determined by the specific requirements of the funding agency. The Office of Sponsored Programs will consult with the Institutional Official and other designated officials as appropriate.

5. Noncompliance: Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Institutional Official, working in conjunction with line supervisory personnel and other designated officials as appropriate, will recommend to the Vice President any appropriate disciplinary actions. Actions may include suspension of all relevant activities or other disciplinary action until the matter is resolved.

The decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with related decisions, will be described in a written explanation of the decision that is sent to the Investigator and the COI Committee, as applicable, and will include notification to the Investigator of the right to appeal the decision.

Retrospective Review

Whenever the Institution determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a

Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, the Institutional Official, working with other designated officials as appropriate, shall within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the sponsored project to determine whether the research activities conducted during the period of non-compliance was biased in the design, conduct or reporting of such research. The Institution will document the retrospective review and its results as required by the funding agency for the affected sponsored project.

If a funding agency requires that the Institution report any Financial Conflict of Interests determined as a result of the retrospective review, the Office of Sponsored Programs will submit the report on behalf of the Institution's Authorized Representative. The report shall include any Financial Conflict of Interests determined as a result of the retrospective review in accordance with regulations of the funding agency. If bias is found through retrospective review, the Office of Sponsored Programs, on behalf of the Institution's Authorized Representative, will notify the funding agency promptly and submit a mitigation report in accordance with regulations of the funding agency. The Office of Sponsored Programs will consult with the Institutional Official and other designated officials as appropriate.

6. Required Training:

All Investigators must complete training and provide proof of completion of training on this Policy prior to engaging in research as required by the funding agency. For projects funded by PHS and the agencies that have adopted the PHS regulations, training is required and must be renewed at least every four years thereafter. Additionally, for projects funded by PHS and the agencies that have adopted PHS regulations, Investigators must also complete training (a) within a reasonable period of time as determined by the Institutional Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, (b) when an investigator is new to the institution, or (c) if it is determined that the Investigator has not complied with this Policy or with a management plan related to their activities.

7. Record Retention:

The Institutional Official will retain all disclosure forms, conflict management plans, training certifications and related documents for a period of three years from the date the final expenditure report is submitted to the funding agency, the date of final resolution of any investigation, audit, or similar action involving the records, or as specifically required by the funding agency, whichever is later.

8. Confidentiality:

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may make such information available to the funding agency, to a requestor of information concerning Financial Conflict of Interests related to applicable agency funding, or to the primary entity who made the funding available to the Institution if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the

Investigator will be informed of this disclosure.

9. Public Accessibility:

The Institution shall make this Policy available on a publicly accessible website.

For projects funded by PHS and the agencies that have adopted the PHS regulations, prior to the expenditure of project funds, the Institution will publish on a publicly accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interests held by PHS Investigators that meet the following criteria:

- a) the Significant Financial Interest was disclosed and is still held by the Investigator;
- b) a determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- c) a determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made publicly available shall be consistent with the requirements of the PHS policy.

Should any other funding agency require public accessibility of Financial Conflict of Interests, the Institution shall provide such public access as required.

10. Subrecipients:

If the sponsored project involves a subrecipient, the Institution will take reasonable steps to ensure that any subrecipient investigator complies with the funding agency's Financial Conflict of Interest policy by incorporating as part of a written agreement, the applicable terms and conditions of the funding agency award.

The Institution will provide a report on subrecipient Financial Conflict of Interest to the funding agency as required by the funding agency.

11. Sources:

U.S. Department of Health and Human Services, Public Health Service (PHS) 42 CFR Part 50; 45 CFR Part 94.

National Science Foundation Proposal and Award Policies and Procedures Guide.

U.S. Department of Agriculture 2 CFR 400.2

Federal Demonstration Partnership (FDP) Model Financial Conflict of Interest Policy.

APPENDIX A

**This list is for informational purposes only and may not be up to date.
Each sponsored project award should be reviewed for sponsor specific FCOI requirements.**

Public Health Service (PHS) Agencies:

Based on the information provided at
<https://www.hhs.gov/about/agencies/orgchart/index.html>,
<http://thefdp.org/default/committees/research-compliance/conflict-of-interest/> and the HHS
Grants Policy Statement.

Administration for Children and Families (ACF)
Administration on Aging
Agency for Healthcare Research and Quality (AHRQ)
Agency for Toxic Substances and Disease Registry
Office of the Assistant Secretary for Health (ASH)
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Centers for Disease Control and Prevention (CDC)
Food and Drug Administration (FDA)
Federal Occupational Health (FOH)
Health Resources and Services Administration (HRSA)
Indian Health Service (IHS)
National Institutes of Health (NIH)
Office of Global Affairs (OGA)
Office of Public Health & Science (OPHS)
Substance Abuse and Mental Health Services Administration (SAMHSA)

Private Sponsors:

Alliance for Lupus Research (ALR)
American Asthma Foundation
American Cancer Society (ACS)
American Heart Association (AHA)
American Lung Association (ALA)
Arthritis Foundation (AF)
CurePSP
Juvenile Diabetes Research Foundation (JDRF)
Lupus Foundation of America (LFA)
Patient-Centered Outcomes Research Institute (PCORI)
Susan G. Komen for the Cure

Other Federal Agencies with FCOI Requirements:

U.S. Department of Agriculture
National Science Foundation