

LOUISIANA STATE UNIVERSITY AGRICULTURAL CENTER

Effective Date: January 17, 1996

AG CENTER PS-29

Version: 0

DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS TO PREVENT BIAS IN RESEARCH

Purpose

To establish guidelines regarding disclosure of financial interests and management of financial conflicts of interest that could bias the outcome of sponsored projects involving research, education, and university service of units of the LSU Agricultural Center.

Background

Effective interaction between universities conducting research and industry is essential to ensure the rapid application of scientific discoveries to the needs of the nation and to maintain the international competitiveness of domestic industry. Numerous statues and programs demonstrate federal interest in the promotion of interactions among government, academia and industry (see Appendix, page 7).

The value of the results of sponsored research to the health and the economy of the nation must not be compromised by any investigator financial interest that could bias the design, conduct or reporting of the research. This policy seeks to maintain a reasonable balance between these competing interests, give the University the ability to identify and manage financial interests that may bias the research, and minimize reporting and other burdens on the investigators.

Policy

This disclosure requirement applies to all new applications for funding to the national Science Foundation and the Public Health Service PHS/NIH/CDC. If it is extended to other agencies in the future, their requirements are hereby incorporated by reference when published.

These guidelines define University policy and procedures regarding disclosure of financial interests and management of financial conflicts of interest that could bias the outcome of sponsored projects involving research, education, and university service. Their primary purpose is to comply with specific agency requirements and, in doing so, to protect the credibility and integrity of the University's faculty and staff so that public trust and confidence in the University's sponsored activities is ensured.

To comply with federal regulations, the institutions must manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of an investigator. Thus, the University requires that investigators disclose all Significant Financial Interests that may present an actual or potential Conflict of Interest related to a sponsored project.

1. DEFINITIONS

A “**potential Conflict of Interest**” occurs when there is a divergence between an individual’s private interests and his or her professional obligations to the University such that an independent observer might reasonably question whether the individual’s professional actions or decisions are influenced or determined by considerations of personal gain, financial or otherwise.

A “**Conflict of Interest**” exists when an Administrative Reviewer and a Special Conflict of Interest Resolution Committee (CIRC) reasonably determine, based on sponsor’s criteria that a Significant Financial Interest exists that could directly and significantly affect the design, conduct, or reporting of the proposed sponsored project. An actual “Conflict of Interest” depends on the situation and not on the character or actions of the individual.

“**Investigator**” means the principal investigator/project director, co-principal investigators, and any other person who is responsible for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding, by an external sponsor.

The term “Investigator” includes the investigator’s spouse and dependent children.

“**Significant Financial Interest**” means anything of monetary value, including, but not limited to:

*salary or other payments for services (e.g., consulting fees or honoraria)

*equity interests (e.g., stocks, stock options or other ownership interests)

*intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term does not include:

a) Salary, royalties, or other remuneration from the University;

b) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;

c) Income from service on advisory committees or review panels for public or nonprofit entities;

d) When an equity interest aggregated for the Investigator (including spouse and dependent children, as defined above) meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not constitute more than a five percent ownership interest in any single entity;

e) Salary, royalties or other payments that when aggregated for the Investigator and the Investigator’s spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.

Provided, however, that the exclusions in items a), d), and e) shall not apply if the compensation or transfer of an equity interest is conditioned upon a particular outcome in a sponsored research project.

2. GUIDELINES FOR DISCLOSURE

Each Investigator is required to disclose the following Significant Financial Interests:

a) Any Significant Financial Interest of the Investigator that would reasonably appear to be directly and significantly affected by the research or educational activities funded, or proposed for funding, by an external sponsor; or

b) Any Significant Financial Interest of the Investigator in an entity whose financial interest would reasonably appear to be directly or significantly affected by the research or educational activities funded, or proposed for funding by an external sponsor.

Note that only financial interests relating to the particular proposal or project currently being submitted to the sponsor need be disclosed.

Regardless of the above minimum requirements, a faculty or staff member in his or her own best interest may choose to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career and the University from potentially embarrassing or harmful allegations of misconduct.

3. PROCEDURES

a) Disclosure: Federal regulations require that all Significant Financial Interests must be disclosed prior to the time a proposal is submitted to NSF/PHS. This will be done at the LSU Agricultural Center when the pro-

posal is routed for approval. Financial disclosures must be updated by Investigators during the period of the award, as new reportable significant Financial Interests are acquired.

A disclosure constitutes a completed Significant Financial Interests Disclosure Form, pertinent documentation describing the financial interests, and a copy of the proposal.

An activity previously approved under PM-11, or a prior PM-67 application, may require disclosure under this policy if it concerns an activity which has the potential to constitute a conflict of interest for the proposed activity: attach a copy of the PM-11 disclosure and an explanation. If an Investigator has applied for or possesses a PM-67 research or licensing agreement, and the proposed activity could affect the prospective value of financial interests of the Investigator which are the subject of the agreement, or could benefit or disadvantage the sponsor of the proposed activity (because of sponsor interests in, or in competition with, the subject of the PM-67 agreement), a copy of the agreement and a disclosure to that effect are also required. Each person who has significant financial interests requiring disclosure must complete a Significant Financial Interests Disclosure Form (example attached), attach all required supporting documentation, and place the materials in a sealed envelope addressed to the Vice Chancellor for Research, the Vice Chancellor for Extension, or the Director of International Programs, as appropriate, and clearly marked "CONFIDENTIAL— Significant Financial Interests Disclosure," identified with the name of the person making

the disclosure, and the project name.

b) PI/PD responsibilities: It is the responsibility of the Principal Investigator/ Project Director to ensure 1) that every named Investigator signs the Proposal Routing Form, so certifying they have read, and they and their family have complied with the disclosure requirement; 2) that all other persons responsible for the design, conduct and reporting of the project have been informed of their obligation to declare any relevant Significant Financial Interests using the LSU Agricultural Center Significant Financial Interests Disclosure Form. (Individuals receiving funding under sub-contracts from LSU are covered under section i).

c) Awards lacking a proposal: In the event that an award subject to this policy is offered without a proposal having been routed through the normal channels, a Proposal Routing Form must be completed (complete with all necessary signatures and disclosures), and resolution of any conflicts of interest attained, prior to expenditure of funds.

d) Initial review: An Administrative Reviewer shall be appointed by the Vice Chancellor for Research, Vice Chancellor for Extension, or Director of International Programs, as appropriate to conduct an initial review of all financial disclosures to determine whether a Conflict of Interest with the potential to bias the project appears to exist. The reviewer may make any inquiries he/she considers necessary to make this determination. Those disclosures deemed to represent a Significant Conflict of Interest by the Administrative Reviewer will then be

referred to the Vice Chancellor for Research, Vice Chancellor for Extension, or Director of International programs, as appropriate, for further action. The Vice Chancellor or Director will appoint a Special Conflict of Interest Resolution Committee (CIRC) for that particular case. If a disclosure is referred to the Special CIRC, the individual concerned and the Project director will be so informed.

e) Special CIRC procedures: If a disclosure is forwarded to the Special CIRC, the Special CIRC shall:

1. Review the disclosure, determine if a Significant Conflict of Interest exists and, if so, make recommendations for resolution. If the Special CIRC determines no further action is required, the Discloser and the appropriate Vice Chancellor or Director will be so informed.

2. If the Special CIRC determines a Significant Conflict of Interest exists which requires resolution, it will so notify the appropriate Vice Chancellor or Director. The Chair of the Special CIRC will work with the individual having a Conflict of Interest to develop a Resolution Plan, which may become a Memorandum of Understanding (MOU) between the individual and the University. Such a Plan shall detail measures to manage, reduce, or eliminate any actual or potential conflict of interest presented by a Significant Financial Interest.

3. The Special CIRC will recommend to the appropriate Vice Chancellor or Director approval, disapproval, or recommended changes in the Resolution Plan.

At a minimum, the Resolution Plan shall address such issues as:

1. Public disclosure of significant financial interests
2. Review of research protocol by independent reviewers
3. Monitoring of research by independent reviewers.

The Special CIRC may require incorporation of such measures in a Resolution Plan as:

1. Modification of the research plan.
2. Disqualification of the Investigator with the conflict from participation in all or a portion of the research.
3. Divestiture of significant financial interests.
4. Severance of relationships that create actual or potential conflicts of interest.
5. Disclosure of the conflict to the sponsor.

The appropriate Vice Chancellor or director shall ultimately determine what conditions or restricts, if any, should be required by the University to manage actual or potential conflicts of interest arising from disclosed Significant Financial Interests, and shall approve the Resolution Plan, when acceptable.

If the Special CIRC determines that imposing specific conditions or restrictions would be inequitable, or that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the Special CIRC may, in exceptional circumstances, recommend (to the extent permitted by federal regulations) that the project go forward without imposing such conditions

or restrictions. In these cases, the appropriate Vice Chancellor or Director shall make the final decision regarding resolution and provide documentation of the ruling to the Special CIRC.

f) Resolution Plan: The Resolution Plan will detail the conditions or restricts to which the Investigator must adhere in the conduct of the project or in the relationship with the Business Enterprise or Entity. The Resolution Plan shall be structured as a Memorandum of Understanding (MOU) between the Investigator and the University. The MOU will be signed by the Investigator, the unit head of the Investigator, and the appropriate Vice Chancellor or Director.

Actual or potential conflicts of interests must be resolved in accordance with these guidelines before any grant funds are expended. If negotiations to reach a resolution plan are incomplete when an aware is made, the appropriate Vice Chancellor or Director will embargo the award to prevent expenditure of funds until the matter is resolved. If a Resolution Plan is not agreed to by the Investigator and the University, the unresolved conflict will be disclosed to the sponsoring agency for action or, at the option of the University, the proposal may be withdrawn or the award declined. The PHS requires the University to report to its awarding component the existence of each conflict of interest (but not its nature) and assure that it has been managed, reduced or eliminated; this will be done by the appropriate Vice Chancellor or Director after the MOU has been signed.

g) Records: The Special CIRC shall maintain minutes for its deliberations. Records of investigator financial disclosures and of

actions taken to manage actual or potential conflicts of interest, shall be turned over to the appropriate Vice Chancellor or Director and maintained for at least 3 years after the termination or completion of the award to which they relate, or the resolution of any university of government action involving those records, whichever is the later.

h) Violations: Whenever an Investigator is discovered to have violated this policy or the terms of the MOU by failing to disclose a significant conflict of interest, or by failing to adhere to the Resolution Plan, the appropriate Vice Chancellor or Director has the option to recommend disciplinary action to the Chancellor, if appropriate. Such action could range from a letter of reprimand to termination. If the violation results in a collateral proceeding under University policies regarding misconduct in science, then the appropriate Vice Chancellor or Director has the option of immediately withdrawing a pending grant application; in addition, possible disciplinary action may be delayed until the misconduct allegations have been investigated.

i) Subcontracts: Subcontractors from other institutions must either comply with this policy by providing a completed Significant Financial Interests Disclosure Form for each employee associated with the project or a certification, signed by an authorized official, that their institution is in compliance with federal policies regarding Investigator Significant Financial Interests disclosure and that their portion of the project is in compliance with their institutional policies. Commercial contractors need not so certify unless the prime award is from the PHS. This requirement will be met as part of the LSU subcontracting process.

j) Appointment of the Special CIRC: Committee members will be appointed by and serve at the pleasure of the appropriate Vice Chancellor or Director on a case-by-case basis. Each Special CIRC shall comprise, at a minimum, four faculty members and an administrator. The Administrative Reviewer shall serve as an ex officio member, and may also serve as the University administrative representative.

k) Confidentiality of Records: Disclosures and records will be maintained in confidence to the extent permitted by law and regulation, and subject to LSU's need to manage potential or actual conflicts of interest and misconduct in science.

4. APPENDIX

a) Regulatory basis for the disclosure requirement:

1. National Science Foundation: Federal Register, July 11, 1995, p. 35820.
2. Public Health Service: Federal Register, July 11 and 31, 1995, pp. 35809 & 39077.

b) Legislative basis for University participation in technology transfer and industry collaborations:

The Stevenson-Wydler Technology Innovation Act of 1980 (Public Law (P.L.) 96-480) encourages technology transfer, particularly through industrial-academic collaborations. The Patent and Trademark Act Amendments of 1980 (P.L. 96-517) allow universities and other funding recipients to apply for patents developed with federal funding, and expressly promote collaboration between commercial concerns and non-profit organizations. The Economic Recovery Tax Act of

1981 (P.L. 97-34) is aimed at fostering research and development by small companies and associated university partners. The Federal Technology Transfer Act of 1986 (P.L. 99-502), which amended P.L. 96-480, and Executive Order 12592 provide similar patent and licensing authority to federal laboratories, and encourage them to participate in cooperative research and development agreements with the private sector and non-profit organizations, including universities.

These legal authorities facilitate the movement of intellectual capital among the federal government, academic institutions, and the private sector because such crossfertilization is critical to the development of U.S. industry. However, these and other inducements for collaboration have created a climate in which the stewardship of public funding for research is increasingly complex and challenging.

Attachments: LSU Agricultural Center Significant Financial Interests Disclosure Form and LSU Agricultural Center Significant Financial Interests Disclosure Policy —Summary