

Policy on Disclosure of Investigator Significant Financial Interests Related to Sponsored Projects

A. Introduction

These guidelines define University policy and procedures regarding conflicts of interest in relationship to sponsored projects involving research, education, and University service. Their purpose is to protect the credibility and integrity of the faculty and staff so that public trust and confidence in the University's sponsored activities is ensured.

In accordance with Federal regulations, the University has a responsibility to *manage, reduce, or eliminate any conflicts of interest* resulting from a financial interest of an Investigator. Thus, **the University requires that Investigators (individuals who have independent responsibility for the design, conduct, or reporting of a project) disclose any significant financial interests that would reasonably appear to present a conflict of interest in a relationship with a sponsor.**

The regulations require a limited and targeted financial disclosure. "Significant financial interests" are defined as interests or annual outside income from a single entity valued at greater than \$10,000 or an equity or ownership interest in a single entity of more than 5% or \$10,000 in value held by an Investigator and the Investigator's spouse and dependent children. Each proposal submitted to a sponsor will require a determination by the Investigator of whether a disclosure is needed **based on the relationship of the work proposed and any significant financial interest.**

Whenever the work to be performed under a sponsored project and the results of the undertaking could reasonably be expected to have an impact on the financial interest, the financial interest is "related" to the sponsored project and must be disclosed. The following are examples of financial interests "related" to a sponsored project:

1. The organization in which the Investigator has a financial interest would manufacture or commercialize any drug, device, procedure, or any other product involved in, or that will predictably result from, the project.
2. The results of the project would be relevant to the development, manufacturing, or improvement of the products or services of the organization in which the Investigator has a financial interest.
3. All income from consulting activity, if it meets the threshold for a financial interest, unless it is clearly unrelated to the Investigator's area of academic expertise.
4. The sponsored project will subcontract a portion of the work, or lease property, or make purchases from an entity in which the Investigator has a financial interest.
5. The sponsored project will involve referral of participants to organizations in which the Investigator has a financial interest, or includes collaboration or participation in a consortium with organizations in which the Investigator has a financial interest.

Financial interests that are not "related" to the sponsored project do not need to be disclosed. For instance, a computer scientist conducting research would disclose any financial interests in companies manufacturing computers, such as IBM, and a medical researcher would disclose any financial interests in pharmaceutical companies, such as Eli Lilly. However, unless the project concerns computer-aided drug design, the computer scientist need not disclose financial interests in Eli Lilly; the medical researcher would normally not need to disclose financial interests in IBM; and neither of them would need to disclose any financial interests unrelated to their field of research (such as K-Mart stock or real estate investments).

The value of the results of sponsored projects to the health and the economy of the Nation must not be compromised by any financial interest that might bias the design, conduct, or reporting of a project. This policy seeks to maintain a reasonable balance between professional obligations and personal interests, to give the University the ability to identify and manage financial interests that may bias a project, and to minimize reporting and other burdens on the Investigators.

B. Background

The National Science Foundation (NSF) and the Department of Health and Human Services (HHS) have issued new regulations, effective October 1, 1995, which require disclosure of Significant Financial Interests by Investigators engaged in a project being proposed to those agencies, when such interests may be affected by the research or other activity being proposed. These regulations require that the University have in place a written and enforced policy on conflict of interest which:

1. requires financial disclosure by Investigators (including interests of their spouses and dependent children) responsible for the design, implementation, and reporting of the proposed research at the time a proposal is submitted;
2. designates an individual(s) to review disclosures, determine whether a conflict exists, and resolve actual or potential problems related to conflicts;
3. requires that financial disclosure be updated annually, or as new reportable financial interests are obtained;
4. provides enforcement mechanisms and sanctions for individuals who fail to comply;
5. provides for notification of the sponsoring agency; and
6. ensures the maintenance of records for at least three years after a project has been completed.

In addition, each proposal will require certification on sponsor forms by the University official who signs the proposal that the University has implemented a written and enforced policy on conflict of interest consistent with sponsor regulations; that to the best of his/her knowledge, all financial disclosures required by that conflict of interest policy have been made; and that all identified conflicts of interest will be satisfactorily managed, reduced, or eliminated before expenditure of any funds under the award.

HHS also requires that, before any expenditures on an award, a report be submitted to the HHS unit issuing the award stating that a conflict of interest exists (but no other details) and assuring that the conflict of interest has been resolved. Any financial interests disclosed **after** the initial report must be reported to the awarding unit within 60 days of identification.

NSF requires a report only if the University is unable to resolve a conflict of interest.

In addition, collaborators from other institutions and non-profits (HHS includes commercial firms) must either comply with the University's policy or provide a certification indicating that they are in compliance with Federal policies on Investigator Significant Financial Interest disclosure and that their portion of the project is in compliance with their policies.

The University expects that other government agencies will follow suit and that there will eventually be a government-wide Common Rule issued. Initially, the Disclosure policy described in the following would apply to proposals submitted to NSF and HHS after September 30, 1995. The expectation is that it will be extended to **all** proposals and applications submitted to external sponsors as required by law.

The Disclosure policy is supplementary to the "Lehigh University Code of Ethical Conduct for University Representatives," which is the University's general conflict of interest policy, and the requirement in section 2.5 of **Rules and Procedures** for disclosure of consulting activities and for reporting to the President activity in private practice or participation as a principal or officer in any partnership or company.

C. **Definitions**

A **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 determined by considerations of personal gain, financial or otherwise. A conflict of interest depends on the situation and not on the character or actions of the individual.

For the purposes of this policy, a conflict of interest exists when the University, through procedures described herein, reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of sponsored projects.

Investigator means the principal investigator/project director, co-principal investigators, and any other person who has independent responsibility for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding, by an external sponsor. In this context, the term "Investigator" includes the Investigator's spouse and dependent children.

Significant Financial Interest means:

1. Income, including salary, consulting payments, honoraria, royalty payments, dividends, or any other payments or consideration with value from a single business entity during the prior twelve months, exceeding \$10,000 when aggregated for the Investigator and the Investigator's spouse and dependent children.
2. Income, including salary, consulting payments, honoraria, royalty payments, or any other payments or consideration with value from a single public or nonprofit entity during the prior twelve months, exceeding \$10,000 when aggregated for the Investigator and the Investigator's spouse and dependent children, **excluding income from seminars, lectures, teaching engagements, or service on advisory committees or review panels.**
3. Equity in the form of stock, stock options, real estate, or any other investment or ownership interest exceeding \$10,000 (current market value if publicly traded, otherwise, amount of investment) or a 5% ownership interest, for any one enterprise when aggregated for the Investigator and the Investigator's spouse and dependent children.
4. A management position, such as director, officer, partner, or trustee, held by the Investigator in any entity.
5. Intellectual property interest held by the Investigator or the Investigator's spouse or dependent children on a patent, patent application, or a copyright of software assigned or to be assigned to a party other than the University.

A Significant Financial Interest does not include salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration from the University.

D. Guidelines

1. Each Investigator is required to disclose the following Significant Financial Interests:
 - (i) Any Significant Financial Interest of the Investigator that would reasonably appear to be affected by the research, educational, or service activities funded, or proposed for funding, by an external sponsor; **or**
 - (ii) Any Significant Financial Interest of the Investigator in an entity whose financial interest would reasonably appear to be affected by the research, educational, or service activities funded, or proposed for funding, by an external sponsor.

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

2. As part of the proposal process, each Investigator will be asked to sign a certification (see Attachment 1) stating whether a Disclosure **is** or **is not** required. This certification is part of the internal Proposal Transmittal Form prepared by the Office of Research and Sponsored Programs (ORSP) for each proposal that is sent to a sponsor. The certification becomes part of the permanent proposal file, and is not submitted to the sponsor.

If all Investigators certify that a Disclosure **is not required**, no further action is necessary.

3. Each Investigator who has a Significant Financial Interest requiring disclosure shall complete a "Disclosure of Investigator Significant Financial Interests Related to Sponsored Projects" form (see Attachment 2). This form is available from the ORSP. The completed Disclosure form must be submitted with the proposal to the ORSP. The completed Disclosure form is kept in a secure file in the ORSP. Disclosure materials are **not** submitted to the sponsor with the proposal.
4. As required by Federal regulation, all Significant Financial Interests must be disclosed *before a proposal is submitted* to a funding agency. All financial disclosures must be updated by Investigators during the period of the award, as new reportable Significant Financial Interests are obtained.
5. The Assistant Vice President for Research and Sponsored Programs (Assistant VP-R&SP) shall conduct an initial review of all Disclosures to determine whether there may be a conflict of interest that requires resolution covered by this policy.

If the disclosed interest is not deemed to present a conflict under this policy, the Assistant VP-R&SP will annotate this on the Disclosure form, and no further action is necessary.

In cases where a conflict **may** exist, the procedure for reviewing and resolving the conflict will be initiated only after an award has been received from the sponsor.

If a proposal is not funded, no further action is necessary.

6. When a proposal is funded and the disclosed interest **may** present a conflict that requires resolution, the Assistant VP-R&SP will notify the Investigator. The Investigator, in cooperation with the academic unit or College, shall develop a Conflict of Interest Resolution Plan and provide it to the Assistant VP-R&SP for initial review.

The Resolution Plan should detail proposed steps that will be taken to manage, reduce, or eliminate any conflict of interest presented by a Significant Financial Interest. At a minimum, the Resolution Plan shall address such issues as:

- (1) Public disclosure of Significant Financial Interests (entity and relationship, but not amount of money);
- (2) Review of research protocol by independent reviewers; **or**
- (3) Monitoring of research by independent reviewers.

If the proposed Resolution Plan is not satisfactory, the Assistant VP-R&SP may return it to the Investigator for revision.

7. The Disclosure packet and proposed Resolution Plan will be referred by the Assistant VP-R&SP to the Conflict of Interest Review Committee (CIRC). (See Attachment 3 for a description of the Committee and its responsibilities.)

A conflict of interest exists when the CIRC reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the proposed sponsored project. The Committee shall determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce, or eliminate conflicts of interest arising from disclosed Significant Financial Interests.

The CIRC will review the Disclosure form and the proposed Resolution Plan and will either approve the Plan or add conditions, such as the following:

- (1) Modification of the research plan;
- (2) Disqualification from participation in all or a portion of the research funded;
- (3) Divestiture of Significant Financial Interest; **or**
- (4) Severance of relationships that create conflicts.

Any changes will be incorporated by the Committee into a revised Resolution Plan. The resulting approved Resolution Plan and Disclosure will be returned to the Assistant VP-R&SP.

If the CIRC determines that imposing the suggested conditions or restrictions would be either ineffective or 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 CIRC may recommend that, to the extent permitted by Federal regulations (HHS policy, for instance, does not permit such actions), the project should go forward without imposing such conditions or restrictions. In these cases, the Provost shall make the final decision regarding resolution.

8. The approved Resolution Plan shall be incorporated into an agreement between Lehigh University and the Investigator that details the conditions or restrictions imposed on the Investigator in the conduct of the project (see Attachment 4). The agreement will be prepared by the Assistant VP-R&SP and signed by the Investigator and, on behalf of the University, the Chair of the CIRC. If an Investigator disagrees with the approved Resolution Plan, the matter will be referred to the Provost for review and resolution.

Conflicts of interest must be satisfactorily managed, reduced, or eliminated in accordance with these Guidelines and all required reports regarding conflict of interest submitted to the sponsor *before any expenditures are charged on an award*.

9. The University will inform the sponsor if it finds that it is unable to satisfactorily manage a conflict of interest. It will be the responsibility of the Investigator(s) and responsible Administrator(s) (e.g., Department Chair, Supervisor, Center Director) to notify the Chair of the CIRC or the Assistant VP-R&SP any time the recommendations of the CIRC cannot be fulfilled. The Assistant VP-R&SP will be responsible for notifying the sponsor.

For awards from HHS, the Assistant VP-R&SP will prepare a report that states that a conflict of interest exists and that the conflict has been resolved. The report will be submitted to the HHS awarding unit. No details concerning the nature of the conflict need to be provided. Any subsequent change in financial interests resulting in a conflict must be resolved and reported to the awarding unit within 60 days of identification.

10. Investigator Disclosure forms and records of actions taken to manage conflicts of interest shall be maintained by the ORSP in a secure file for at least three years after the termination or completion of the award to which they relate, or the resolution of any government action involving those records, whichever is longer.
11. The University will exert reasonable efforts to keep all transactions pertaining to Disclosure forms secure. The information supplied will be released internally only to the extent needed to comply with the University's policy and procedures on Investigator disclosure. Under federal law (45CFR74.53), federal sponsors have the right to review this material. Investigators will be informed of any request from a federal sponsor to release this information.
12. Collaborators/subrecipients/subcontractors from other academic or not-for-profit institutions must either comply with this policy or provide a certification that their institutions are in compliance with Federal policies regarding Investigator Significant Financial Interest disclosure and that their portion of the project is in compliance with their institutional policies. Subcontractors from commercial firms need not make a certification, except when the prime award is from HHS. HHS requires a certification from any subcontractor, including commercial firms, stating that it is in compliance with Federal policies regarding Investigator Significant Financial Interest disclosure and that its portion of the project is in compliance with company policies. This information will be obtained by the respective Research Administrator in the ORSP before the proposal is submitted.

E. Enforcement and Sanctions

Failure to file a complete Disclosure form or to provide the required updates, or to comply with any conditions or restrictions imposed on the conduct of the project, will be grounds for discipline under applicable University employee policies.

In addition, the University shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved.

A complaint alleging that an Investigator has violated this policy or failed to comply with the decision of the CIRC for the management, reduction, or elimination of a conflict should be brought to the attention of the Chair of the CIRC or the Assistant VP-R&SP. Although the procedure for handling a complaint will depend upon the particulars of the complaint, normally the CIRC will interview the person bringing the complaint and the Investigator who is alleged to have violated the policy or failed to comply with a decision. If the complaint is not resolved or the violation or failure to comply remedied **informally** by the CIRC, then the matter will be referred by the Provost to the appropriate University review committee for further action. If the violation results in a collateral proceeding under University policy regarding misconduct in science, then a decision on sanctions should be deferred until the misconduct in science process is completed.

F. Reporting of Changes in Significant Financial Interests

The responsibility rests with each Investigator to update information when there is a change in his/her Significant Financial Interests. Disclosures must be updated annually, or as changes occur.

As a reminder to Investigators to report at least annually, the "Acknowledgment of the University's Code of Ethical Conduct" will contain a section requesting supplemental information on changes in financial interests from all faculty and staff who are participating in a sponsored project or who have a proposal pending with a sponsor.

The "Acknowledgement" is sent over the network by the Internal Audit Office each year and must be completed by all University Representatives, a category which includes faculty and staff participating in sponsored projects. All replies to the Auditor are confidential. However, if a change in Significant Financial Interests is indicated, the Auditor will inform the Assistant VP-R&SP that a revised Disclosure is needed, and the Investigator will be asked to submit an updated Disclosure form.

ATTACHMENT I

PROPOSAL TRANSMITTAL FORM

CONFLICT OF INTEREST
Certification for Investigator Significant Financial Interest Disclosure Policy

The following certification requests a declaration from each Investigator independently involved in the design, conduct, or reporting of the proposed project that the project or relationship with this sponsor either REQUIRES or DOES NOT REQUIRE the disclosure of significant financial interests that might present a conflict of interest.

I certify that I:

- Have read and understood Lehigh University's Investigator Significant Financial Interest Disclosure Policy and agree to comply with this policy, and
Agree to update the information if my financial interests change.

Furthermore, if a financial disclosure is required, I:

- Will complete a Significant Financial Interest Disclosure form and all required attachments and provide this material with the proposal.

I certify that, to the best of my knowledge, the proposed project or relationship:

- Does NOT require disclosure.
DOES require disclosure. A completed Significant Financial Interest Disclosure form with supporting materials is attached.
DOES require disclosure. An applicable disclosure was submitted with proposal no. _____.

Investigator Signature: _____ Date: _____
Typed: _____

- Does NOT require disclosure.
DOES require disclosure. A completed Significant Financial Interest Disclosure form with supporting materials is attached.
DOES require disclosure. An applicable disclosure was submitted with proposal no. _____.

Investigator Signature: _____ Date: _____
Typed: _____

SUMMARY OF POLICY FOR DISCLOSURE OF INVESTIGATOR SIGNIFICANT FINANCIAL INTERESTS RELATED TO SPONSORED PROJECTS

What is Required?

Federal regulations require institutions to have policies and procedures in place that ensure that Investigators disclose any significant financial interest that may present a conflict of interest in relationship to externally sponsored projects. Such disclosures must be made **before the submission of a proposal** for funding,* and institutions must develop specific mechanisms by which conflicts of interest will be satisfactorily managed, reduced, or eliminated **before any funds are expended from an award**.

The University has developed a **Policy for Disclosure of Investigator Significant Financial Interests Related to Sponsored Projects** in response to these Federal regulatory requirements. The Disclosure policy is supplementary to the "Lehigh University Code of Ethical Conduct for University Representatives," which is the University's general conflict of interest policy, and the requirement in section 2.5 of **Rules and Procedures** for disclosure of consulting activities and for reporting to the President activity in private practice or participation as a principal or officer in any partnership or company.

- * If a new reportable conflict of interest occurs at any time after the submission of the proposal or during the period of the award, the filing of a disclosure is also required.

Who is covered?

"Investigator" means the principal investigator/project director, co-principal investigators, and any other University employee who has independent responsibility for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding, by an external sponsor. In this context, the term "Investigator" includes the Investigator's spouse and dependent children.

What must be disclosed?

Each Investigator must disclose all *significant financial interests*:

- (i) that would reasonably appear to be affected by the research, educational, or service activities funded, or proposed for funding, by an external sponsor; **or**
- (ii) in entities whose financial interest would reasonably appear to be affected by such activities.

What is a "significant financial interest?"

"*Significant financial interest*" means:

1. Income, including salary, consulting payments, honoraria, royalty payments, dividends, or any other payments or consideration with value from a single business entity during the prior twelve months, exceeding \$10,000 when aggregated for the Investigator and the Investigator's spouse and dependent children.
2. Income, including salary, consulting payments, honoraria, royalty payments, or any other payments or consideration with value from a single public or nonprofit entity during the prior twelve months, exceeding \$10,000 when aggregated for the Investigator and the Investigator's spouse and dependent children, **excluding income from seminars, lectures, teaching engagements, or service on advisory committees or review panels.**
3. Equity in the form of stock, stock options, real estate, or any other investment or ownership interest exceeding \$10,000 (current market value if publicly traded, otherwise, amount of investment) or a 5% ownership interest, for any one enterprise when aggregated for the Investigator and the Investigator's spouse and dependent children.
4. A management position, such as director, officer, partner, or trustee, held by the Investigator in any entity.
5. Intellectual property interest held by the Investigator or the Investigator's spouse or dependent children on a patent, patent application, or a copyright of software assigned or to be assigned to a party other than the University.

A Significant Financial Interest does not include salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration from the University.

What is a "financial interest related to a project?"

Whenever the work to be performed under a sponsored project and the results of the undertaking could reasonably be expected to have an impact on the financial interest, the financial interest is "related" to the sponsored project and must be disclosed. The following are examples of financial interests "related" to a sponsored project:

1. The organization in which the Investigator has a financial interest would manufacture or commercialize any drug, device, procedure, or any other product involved in, or that will predictably result from, the project.
2. The results of the project would be relevant to the development, manufacturing, or improvement of the products or services of the organization in which the Investigator has a financial interest.
3. All income from consulting activity, if it meets the threshold for a financial interest, unless it is clearly unrelated to the Investigator's area of academic expertise.
4. The sponsored project will subcontract a portion of the work, or lease property, or make purchases from an entity in which the Investigator has a financial interest.
5. The sponsored project will involve referral of participants to organizations in which the Investigator has a financial interest, or includes collaboration or participation in a consortium with organizations in which the Investigator has a financial interest.

Financial interests that are not "related" to the sponsored project do not need to be disclosed. For instance, a computer scientist conducting research would disclose any financial interests in companies manufacturing computers, such as IBM, and a medical researcher would disclose any financial interests in pharmaceutical companies, such as Eli Lilly. However, unless the project concerns computer-aided drug design, the computer scientist need not disclose financial interests in IBM; and neither of them would need to disclose any financial interests unrelated to their field of research (such as K-mart stock or real estate investments).

What are the Disclosure procedures?

1. As part of the proposal process, each Investigator will be asked to sign a certification stating whether he/she has a significant financial interest related to the project being proposed. The certification is part of the internal Proposal Transmittal Form prepared by the Office of Research and Sponsored Programs (ORSP) for each proposal sent to a sponsor. If all Investigators certify that a Disclosure **is not required**, no further action is necessary. The transmittal form is not sent to the sponsor.
2. Investigators who certify that they **do** have a significant financial interest requiring disclosure must complete the ORSP's **Disclosure of Investigator Significant Financial Interests Related to Sponsored Projects** form. The completed form must be submitted with the proposal to the ORSP. The Disclosure form will be kept in a secure file in the ORSP. Disclosure materials are **not** submitted with the proposal to the sponsor. In accordance with Federal regulations, a complete disclosure must be made by Investigator(s) *before submission of the proposal to the sponsoring agency*.
3. The Disclosure form will be reviewed by the Assistant VP-R&SP to determine whether any reported financial interest would reasonably appear to be directly and significantly affected by the sponsored project. A direct impact occurs when the project results would be directly relevant to the development, manufacturing, or improvement of the products or services of the organization in which the employee has a financial interest. A significant impact on the financial interest is one which will materially affect the value of the organization, its earnings, or the sales of its products. The form provides the opportunity for the Investigator to indicate whether he/she believes the project could directly and significantly affect the financial interest. Based on the information provided on the form, the Assistant VP-R&SP may determine that there is no reasonable basis to conclude that the project could have a direct and significant effect on the Investigator's financial interests such that controls on the project may be necessary to manage or eliminate any potential conflict of interest, in which case the project can be proceed without further review.
4. **When a proposal is funded**, and the Assistant VP-R&SP concluded that the project might have a direct and significant impact on the Investigator's financial interests that requires further review and possible action, the issue will be forwarded for consideration to the Conflict of Interest Review Committee (CIRC). This Committee makes the final determination as to whether a conflict of interest exists and makes a final recommendation about conditions or restrictions that should be placed on the project to manage, reduce, or eliminate the conflict of interest.
5. Resolution of conflicts of interest will be incorporated into an agreement between the Investigator(s) and the University [signed by Investigator(s) and the Chair of the Conflict of Interest Review Committee] *before any funds are expended from an award*.

What will happen in the case of violations?

Failure to file a complete Disclosure form or update, or to comply with any conditions or restrictions imposed on the conduct of the project, will be grounds for discipline under applicable University employee policies. Further, sponsors may suspend or terminate an award in the event of failure to comply with applicable Federal regulations on disclosure.

Attachment 2

Proposal No.: _____

Principal Investigator: _____

LEHIGH UNIVERSITY
Disclosure of Investigator Significant Financial Interests Related to Sponsored Projects
COVER SHEET

Name _____

Department/Unit _____

Proposal Title _____

Proposal Submitted to _____

Your Position on Project PI Co-PI Other

List below the name of each entity in which you have a related significant financial interest and attach a separate DESCRIPTION OF FINANCIAL INTEREST for each entity.

I agree:

- To update this disclosure during the period of the award as new reportable significant financial interests are obtained or on an annual basis.
- To cooperate in the development of an agreement that constitutes a conflict of interest "resolution plan."
- To comply with any conditions or restrictions imposed by the University to manage, reduce, or eliminate conflicts of interest.

Certification

I certify that the above information is complete and true to the best of my knowledge. This information is provided with the understanding that the University will exert reasonable efforts to keep the information secure. The information will be released internally only to the extent needed to comply with the University's policy and procedures on Disclosure. Under federal law (45CFR74.53), federal sponsors have the right to review this material. I will be informed of any request to release this information.

Signature: _____

Date: _____

Provision of the information on this form is mandatory for any person who wishes to be an Investigator on a research, educational, or service project. The principal purpose of collecting this information is to comply with federal regulations and the University Policy on Disclosure of Investigator Significant Financial Interests Related to Sponsored Projects. For further information about the Policy and use of the information, contact the Assistant Vice President for Research and Sponsored Programs, (610) 758-3021.

REVIEWING OFFICIAL'S ACTION

- No Further Review Required (Sponsored project will not reasonably be expected to have a direct and significant impact on these financial interests, such that the financial interests could affect the design, conduct, or reporting of the project.)

- Refer to Conflict of Interest Review Committee (Sponsored project may reasonably be expected to have a direct and significant impact on these financial interests, such that the financial interests could affect the design, conduct, or reporting of the project. Further review required.)

Signature

Date

Proposal No.: _____

Principal Investigator: _____

LEHIGH UNIVERSITY
Disclosure of Investigator Significant Financial Interests Related To Sponsored Projects
DESCRIPTION OF FINANCIAL INTEREST

- **NAME OF ENTITY** _____ *Date* _____
- Type of Entity Business Non-Profit Governmental Other
- Income in past 12 months \$10,001-\$20,000 \$20,001-\$50,000 Above \$50,000
Source: Honoraria Consulting Salary Dividends Spouse or Child's Earnings Other
- Equity (stock, stock option, real estate, investment, or other ownership)
Value \$10,001-\$100,000 \$100,001-\$1,000,000 Above \$1,000,000
% Ownership Below 5% 5-50% Above 50%
- Do you hold a position of management, such as Assistant VP-R&SP, officer, partner, or trustee?
 Yes No
- Does Entity hold copyright of software or patent rights to an invention of yours, your spouse, or dependent child?
 Yes No
- Does Entity hold license rights from Lehigh University to your invention? Yes No
- Is Entity proposed subcontractor, consortium member, supplier of goods, lessor, or otherwise involved with the sponsored project? Yes No
- Does or will the Entity manufacture or commercialize any drug, vaccine, device, procedure, or any other product involved in or that will predictably result from the project? Yes No
- Is it reasonable to anticipate that the sponsored project will have a direct and significant effect on the Entity? Yes No Don't Know

Explanation (optional):

Other Comments, if any: _____

(Retention: Three (3) years after termination of sponsored project or until resolution of any action by the sponsor, which ever is longer.)

Attachment 3

GUIDELINES FOR CONFLICT OF INTEREST REVIEW COMMITTEE

COMMITTEE RESPONSIBILITIES

The Conflict of Interest Review Committee reviews Significant Financial Interest Disclosure forms and makes the final determination as to whether a conflict of interest exists under the University's Policy on Disclosure of Investigator Significant Financial Interest Related to Sponsored Projects. A conflict of interest exists when the CIRC reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the proposed sponsored project.

If a conflict exists, the CIRC reviews the Resolution Plan proposed by the Investigator and makes recommendations, in the form of an approved Resolution Plan, for managing, reducing, or eliminating the conflict.

The CIRC also reviews complaints alleging that an Investigator has violated the Disclosure policy or the agreement to resolve the conflict. If the complaint is not remedied informally by the CIRC, the matter will be referred via the Provost's Office to the appropriate University review committee for further action. The proceedings of the CIRC are confidential.

MEMBERSHIP

The CIRC is a standing committee whose members are appointed by the Provost. The CIRC shall have, at a minimum, four faculty members, representing a cross section of academic disciplines, and an administrator as voting members. Faculty members are expected to serve as members of the University and not as advocates for specific schools or constituencies. The CIRC is chaired by a faculty member appointed by the Provost. All committee members have voting rights. Other attenders participate in discussion but do not vote.

MEETINGS

Attendance. Meetings are limited to CIRC members and other invitees, and are not open to the public.

Quorum. A quorum consists of over half of all voting members. In general, an attempt will be made to ensure that there is a quorum present at all meetings. The CIRC Chair, at her/his discretion, may require that certain decisions be approved by a majority of all voting members, not just a majority of those attending a specific meeting. Final versions of recommendations will usually be approved by mail/FAX in order to ensure that all voting members have an opportunity to register their opinions.

CONFLICTS FOR COMMITTEE MEMBERS

A CIRC member is recused from discussion of a particular case under the following conditions: (1) the case involves a member of the same department; (2) the CIRC member has a personal interest because of interdepartmental relationships, such as collaboration with the faculty member whose case is under consideration; (3) the CIRC member has a fiscal interest in the case under discussion. Special exceptions to these guidelines may be made, but only with the prior approval of a majority of the voting members.

ATTACHMENT 4

Lehigh University Agreement for the Management of Conflict of Interest

Name: _____ Department: _____

Title: _____

Date of Significant Financial Interest Disclosure: _____

I have read the attached Resolution Plan, which has been approved by the Conflict of Interest Review Committee (CIRC), on how the conflict of interest disclosed in my Significant Financial Interest Disclosure can be managed, reduced, or eliminated and (check one of the following):

A. I agree with the Resolution Plan and will abide by the recommendations included in it.

B. I do not agree with the Resolution Plan. However, I believe the conflict of interest can be resolved as follows:

C. I do not agree with the Resolution Plan and request that it be reviewed by the Provost.

Investigator:

Lehigh University:

By: _____
Chair, Conflict of Interest Review Committee

Date: _____

Return: Assistant Vice President for Research & Sponsored Programs

This will be included with Internal Audit's annual Acknowledgment of the Code of Ethical Conduct. For information only -- not part of the Policy.

Supplemental information required from any faculty or staff member who is participating in a sponsored project or who has a proposal for a project pending with a sponsor:

List below any changes in significant financial interests* that have occurred over the past year, or since a proposal was submitted for outside support, which may have created a conflict of interest.

If there are no changes, indicate "None".

***Significant Financial Interest** means:

1. Income, including salary, consulting payments, honoraria, royalty payments, dividends, or any other payments or consideration with value from a single business entity during the prior twelve months, exceeding \$10,000 when aggregated for the Investigator and the Investigator's spouse and dependent children.
2. Income, including salary, consulting payments, honoraria, royalty payments, or any other payments or consideration with value from a single public or nonprofit entity during the prior twelve months, exceeding \$10,000 when aggregated for the Investigator and the Investigator's spouse and dependent children, **excluding income from seminars, lectures, teaching engagements, or service on advisory committees or review panels.**
3. Equity in the form of stock, stock options, real estate, or any other investment or ownership interest exceeding \$10,000 (current market value if publicly traded, otherwise, amount of investment) or a 5% ownership interest, for any one enterprise when aggregated for the Investigator and the Investigator's spouse and dependent children.
4. A management position, such as Assistant VP-R&SP, officer, partner, or trustee, held by the Investigator in any entity.
5. Intellectual property interest held by the Investigator or the Investigator's spouse or dependent children on a patent, patent application, or a copyright of software assigned or to be assigned to a party other than the University.

A Significant Financial Interest does not include salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration from the University.

CERTIFICATION

Regarding Investigator Financial Disclosure Policy/Objectivity in Research

This is to certify that Lehigh University is in compliance with Federal policies regarding investigator significant financial interest disclosure and that the project proposed herein is in compliance with the University's written and enforced policy, "Disclosure of Investigator Significant Financial Interests Related to Sponsored Projects."

LEHIGH UNIVERSITY

By: _____
Richard H. Sanders, Assistant Vice
President for Research and Sponsored
Programs

Dated: _____