

# **Procedures Supplemental to University Policy 101.24, Conflicts of Interest and Commitment**

## Online COI Reporting

### **I. Submission of Conflict Evaluation Forms**

1. All Covered Persons, even if on leave if that leave is funded at least partially from University sources, are required to complete and submit the Annual Evaluation Form for Possible Conflict of Interest or Commitment ("Conflict Evaluation Form") before October 1 each year on a schedule announced by the Provost. All such forms must be submitted to the Department Head. *Updated forms must also be submitted throughout the year as appropriate* (for example, no later than the time of application for or participating in PHS-funded research, the time of assumption of new University Employment Responsibilities, or the time of implementing changes in external professional activities) that may either: (a) give rise to a potential conflict of interest; (b) eliminate a potential conflict previously disclosed; or (c) result in an affirmative answer to any question previously answered in the negative on the Conflict Evaluation Form. Part-time or nine-month employees are covered by these Procedures insofar as their University Employment Responsibilities are concerned.
2. Faculty members and EPA staff employees, as well as other personnel identified as Covered Persons, will be reminded annually to complete and to return Conflict Evaluation Forms, and will be encouraged to seek assistance from their Department Head, Dean or Director, or the Office of Legal Affairs, if questions or special circumstances arise.
3. The Conflict Evaluation Forms contain information that may have a direct bearing on the individual's employment. The forms, therefore, will be included in the individual's personnel file as well as in a database with access limited to University individuals having a need to know the disclosed information. As a part of the personnel file, the forms will be considered confidential unless other treatment is required or allowed by law or regulation. Covered Persons participating in any project funded by the PHS should be aware that as a condition of such participation the PHS will have access to the employee's Conflict Evaluation Forms at any time during the project and for a period of three years after the submission of a final expenditures report for that project to the PHS. Except as otherwise noted in these Procedures, for Financial Interests that are identified as PHS Financial Conflicts of Interest, the information disclosed in the Conflict Evaluation Forms is available only to individuals duly charged with the responsibility for review and conflict management, and the information may be released only in accordance with and as required or allowed by North Carolina law or lawful court order.

### **II. Review and Approval of Conflict Evaluation Forms**

The COI Manager has the initial responsibility to review the Conflict Evaluation Forms filed by each Covered Person. Review must follow the provisions of University Policy 101.24 and these Procedures. The COI Manager is encouraged to consult with a Covered Person's Department Head regarding any Financial Interest activity which the COI Manager feels may give rise to a conflict of interest or commitment. The COI Manager must refer to the Covered Person's Dean or equivalent any Financial Interest or activity that the COI Manager determines constitutes an actual conflict of interest or commitment. In the event that the Covered Person's Dean disagrees with the COI Manager's determination that a Financial Interest constitutes a conflict of interest, the Standing Committee on Conflicts of Interest and Commitment shall determine whether that Financial Interest constitutes a conflict of interest; *provided, however, that until the time that the Standing Committee makes its determination, a conflict of interest shall be deemed to exist from the time the COI Manager determines that the Covered Person's Financial Interests could directly and significantly affect Covered Person's University Employment Responsibilities.*

A Dean, the appropriate Vice Chancellor, or the Chancellor may at any time require the COI Manager to perform a de novo review of any Financial Interest or activity of any Covered Person under their supervision should the Dean, Vice Chancellor, or Chancellor believe that the Financial Interest or activity may constitute a previously unidentified conflict of interest or commitment or that it is in the best interests of the University to do so. Following any such de novo review, the COI Manager will provide a written report describing the COI Manager's findings as to why that Financial Interest or activity does or does not constitute a conflict of interest or commitment.

The Dean or equivalent, the appropriate Vice Chancellor, or the Chancellor may at his or her discretion refer any Financial Interest or activity that has been identified by the COI Manager as constituting a conflict of interest or commitment to the Standing Committee on Conflicts of Interest and Commitment for its recommendation prior to making a decision on whether the Financial Interest or activity constitutes a conflict of interest or instituting a management plan.

In the case of Covered Persons who hold administrative positions, the annual and interim conflict evaluation and review process will proceed as follows:

1. The COI Manager will work with the appropriate Dean or equivalent regarding any Financial Interest or activity which the COI Manager determines to constitute a conflict of interest or commitment and which was disclosed by a Department Head;
2. The COI Manager will work with the appropriate Vice Chancellor regarding any Financial Interest or activity which the COI Manager determines to constitute a conflict of interest or commitment and which was disclosed by a Dean or equivalent; and
3. The COI Manager will work with the Chancellor regarding any Financial Interest or activity which the COI Manager determines to constitute a conflict of interest or commitment and which was disclosed by a Vice Chancellor or other person reporting directly to the Chancellor.
4. The chair of the Standing Committee on Conflicts of Interest and Commitment shall review any disclosures of financial activities or activities by the COI Manager, and shall work with the COI Manager in managing any conflicts of interest and commitment identified in the course of that review.

### **III. Standing Committee on Conflicts of Interest and Commitment**

The Chancellor shall appoint the Standing Committee on Conflicts of Interest and Commitment. The Committee is responsible for reviewing cases that are brought to its attention by a Dean or equivalent, a Vice Chancellor or the Chancellor. It will conduct a thorough review of each case and will make recommendations for conflict resolution to the official who referred the matter to it.

In any case so brought before the Committee, the Covered Person will be provided the opportunity to respond in person and in writing to the issues raised in the course of such review. Any such written response will be appended to the Committee's report for review by the referring official.

In addition, the Committee must meet at least twice in each academic year to review any conflict of interest management plans instituted since the prior meeting of the Committee. The Committee must also take whatever steps it deems reasonable to ensure consistency in the COI Manager's determinations of the existence of conflicts of interest and commitment, including at a minimum a review of a representative sampling of Conflict Evaluation Forms submitted since the prior meeting of the Committee and the COI Manager's basis for determining the existence, or lack thereof, of conflicts of interest and commitment. Meetings of the Committee will observe such formalities as may be necessary to ensure the confidentiality of Conflict Evaluation Forms and other confidential personnel information.

### **IV. Identification and Management of Conflicts of Interest**

Once a Conflict of Interest is identified through the submission of a Conflict Evaluation Form or otherwise, the COI Manager, working with the Covered Person's Department Head, collects all relevant information necessary to make an informed judgment on the matter and presents this information to the Covered Person's Dean or equivalent. The Dean or equivalent decides whether to accept or reject the COI Manager's determination of whether a potential conflict of interest constitutes an actual conflict of interest or commitment. For each actual conflict of interest the Dean or equivalent, working with the COI Manager, develops, documents, and implements an appropriate management plan to address that conflict.

At the Dean's discretion, the Dean may ask the Standing Committee on Conflicts of Interest and Commitment and/or other individuals within or outside of the University to make recommendations regarding any potential or actual conflict of interest and/or any management plan.

The Dean or equivalent may conclude that while a conflict appears to exist, the nature and degree of conflict found to be present are not significant and do not warrant action beyond the initial disclosure and documentation. Where the Dean or equivalent concludes that a management plan is needed, the Dean or equivalent approves and has responsibility for implementing each such management plan. The COI Manager must report all identified conflicts of interest and management plans, including at a minimum the documentation described below, to the Provost.

Components of a management plan may include, but are not limited to:

1. Concluding that while a conflict appears to exist, the nature and degree of the conflict found to be present are not significant and do not warrant action beyond the initial disclosure and documentation.
2. Requiring public disclosure of financial interests.
3. Requiring that the research or other activity be monitored by neutral, independent reviewers.
4. Requiring modification of the research plan or work plan.
5. Requiring that an individual with a conflicting interest be disqualified from participation in a particular project or activity or specified parts of the project or activity.
6. Requiring divestiture or severance of significant financial or other interests that create conflict with the individual's University Employment Responsibilities.

Documentation of the management plan must include at a minimum the following information:

1. The name of the Covered Person who has the conflict of interest.
2. The name of the entity with which the Covered Person has the conflict of interest.
3. The nature of the conflict of interest (e.g., equity interest, consulting fee, travel reimbursement, honorarium).
4. The value of the financial interest or a statement that the interest is one whose value cannot be readily determined through reasonable measures of fair market value. The value may be reported as falling within one of the following ranges:
  - a. \$0 to \$4,999;
  - b. \$5,000 to \$9,999;
  - c. \$10,000 to \$19,999;
  - d. \$20,000 to \$100,000 by increments of \$20,000; and
  - e. amounts above \$100,000 by increments of \$50,000.
5. A description of the key elements of the management plan including:
  - a. The conditions of the management plan.
  - b. Confirmation of the Covered Person's agreement to the management plan.
  - c. How the management plan will be monitored to ensure compliance by the Covered Person.
  - d. Other information as needed.
6. If applicable, the project number(s) of any federally funded projects that the Dean or equivalent feels are related to the conflict.
7. If applicable, the title of each such project.
8. If applicable, the name(s) of the Principal Investigator(s) or Project Director(s) on any such project(s).
9. If applicable, the following additional information about the management plan:
  - a. A description of how the financial interest relates to any federally funded project and the basis of the decision that the financial interest conflicts with the project.
  - b. The role and principal duties of the Covered Person in each such project.
  - c. A description of how the management plan is designed to safeguard objectivity in the research project(s).

## **V. Special Rules for Applicants for or Participants In PHS-Funded Research**

### **A. Subrecipients of PHS-Funded Research Grants**

If the University carries out Public Health Service (PHS)-funded research through a subrecipient such as a subcontractor or a consortium, the University must ensure via written agreement that the subrecipient either follows University Policy 101.24 and these Procedures or a financial conflict of interest policy of the subrecipient. If the subrecipient complies with its own financial conflict of interest policy, the University and the subrecipient must, prior to subrecipient's performance of any PHS-funded work, enter into a written agreement:

1. certifying that the subrecipient's conflict of interest policy complies with the PHS regulations for promoting objectivity in research as codified at Title 42 of the Code of Federal Regulations, Part 50, Subpart F, and
2. specifying the time period(s) for the subrecipient to report all financial conflicts of interest identified under its policy to the University, ensuring that those time period(s) are sufficient to allow the University to provide complete and timely reports to the PHS.

Alternatively, the University and the subrecipient may enter into a written agreement:

1. acknowledging that the subrecipient's employees who are responsible for the design, conduct, or reporting of the PHS-funded research are subject to University Policy 101.24 and these Procedures, and
2. specifying the time period(s) for the subrecipient to submit to the University disclosures of PHS Significant Financial Interest's from subrecipient's employees who are responsible for the design, conduct, or reporting of the PHS-funded research, ensuring that those time period(s) are sufficient to allow University to comply timely with its review, management, an reporting obligations to the PHS.

## **B. Training of Covered Persons Applying for or Participating in PHS Funded Research**

All Covered Persons applying for PHS-funded research grants or participating in PHS-funded research shall complete training provided by the University in PHS regulations for promoting objectivity in research prior to participating in research related to any PHS-funded grant and at least every four years thereafter for so long as they continue to apply for PHS-funded grants or participate in PHS-funded research. In addition, such Covered Persons must also complete such training whenever

1. the University revises University Policy 101.24 and these Procedures in a manner that affects the requirements of Covered Persons;
2. the Covered Person is new to the University; or
3. the University finds that the Covered Person is not in compliance with University Policy 101.24 and/or these Procedures or any management plan developed under these Procedures.

## **C. Disclosure of Sponsored or Reimbursed Travel**

When reporting reimbursed or sponsored travel as required under University Policy 101.24 and these Procedures, the Covered Person must provide at a minimum the following information:

1. The purpose of the trip;
2. The identity of the sponsor and/or organizer of the trip;

3. The destination; and
4. The duration of the trip.

The Dean or equivalent may require disclosure of additional information such as the monetary value of any such travel.

#### **D. Timing of Disclosures of Financial Interests for Covered Persons Applying for or Participating in PHS-Funded Research**

In addition to the annual disclosures required under University Policy 101.24 and these Procedures, any Covered Person applying for PHS-funded research grants must update his or her Conflict Evaluation Form to disclose or update as needed all PHS Significant Financial Interests no later than the time of applying for the PHS-funded research grant. Each Covered Person participating in PHS-Funded Research must also update his or her Conflict Evaluation Form within 30 days of discovering or acquiring (for example, through inheritance or marriage or participating in sponsored or reimbursed travel) a new PHS Significant Financial Interest.

#### **E. Review of PHS Significant Financial Interests**

In reviewing a Covered Person's PHS Significant Financial Interests, the designated University officials first determine whether any PHS Significant Financial Interest is related to the Covered Person's PHS-funded research. The PHS Significant Financial Interest is related to a PHS-funded research project if the designated official(s) determine that the PHS Significant Financial Interest could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the PHS-funded research.

If the PHS Significant Financial Interest is determined to be related to PHS-funded research then the designated University official(s) shall determine whether the PHS Significant Financial Interest constitutes a PHS Financial Conflict of Interest and, if so, the designated University official(s) shall follow the procedures described in this Policy to develop, document, and implement an appropriate management plan. The University shall monitor the Covered Person's compliance with the management plan on an ongoing basis until completion of the PHS-funded project.

For any new PHS-funded project, the review of all relevant disclosures of Financial Interests and implementation of any management plans must be complete prior to expenditure of any funds for the project. For a Covered Person who is new to the PHS-funded project or any Covered Person who discloses a new PHS Significant Financial Interest after the start of the project, review of the disclosure of Financial Interests and implementation of the management plan, if any, must be complete within 60 days of disclosure.

#### **F. Reporting of PHS Financial Conflicts of Interest to the PHS**

For any PHS Financial Conflict of Interest identified and not eliminated, the University must provide the PHS with a report including sufficient information to enable the PHS awarding component to understand the nature and extent of the financial conflict and to assess the appropriateness of the University's management plan, including all documentation of any management plan as described in these Procedures.

The initial report must be submitted prior to any expenditure of funds. After the initial report has been submitted, annual reports must be submitted for each PHS Financial Conflict of Interest for the duration of the project (including funded or unfunded extensions) concurrent with the University's submission of the annual progress report, multi-year progress report (if applicable), or at the time of extension. The annual reports must address the status of each relevant PHS Financial Conflict of Interest and any changes to the management plan, and they must specify whether the PHS Financial Conflict of Interest is still being managed or explain why the PHS Financial Conflict of Interest no longer exists.

If a Covered Person who is newly participating in a project is identified as having a PHS Financial Conflict of Interest, or if any Covered Person participating in a PHS-funded project discloses a new PHS Significant Financial Interest that is determined to be a PHS Financial Conflict of Interest after the start of the project, a report of that PHS Financial Conflict of Interest, including documentation of its associated management plan, must be sent to the PHS awarding component within 60 days after the PHS Financial Conflict of Interest has been identified.

### **G. Disclosure of PHS Financial Conflicts of Interest to the Public**

Prior to the expenditure of PHS funds the University must ensure public accessibility, in response to written request within five (5) business days of receipt of the request, to information concerning PHS Financial Conflicts of Interest that are currently held by Covered Persons. The information the University must disclose must be updated at least annually, must be maintained for a period of three years from the last update, and must include the following data elements at a minimum:

1. Name of the Covered Person;
2. Title of the Covered Person;
3. Role of the Covered Person with respect to the relevant research project;
4. Name of the entity in which the significant financial interest is held;
5. Nature of the PHS Financial Conflict of Interest; and
6. Approximate dollar value of the significant financial interest (the following dollar ranges are permissible: \$0 to \$4,999; \$5,000 to \$9,999; \$10,000 to \$19,999; \$20,000 to \$100,000 by increments of \$20,000; and amounts above \$100,000 by increments of \$50,000), or a statement if the interest is one whose value cannot be readily determined through to public prices or other reasonable measures of fair market value.

### **H. PHS Financial Conflicts of Interest That Were Not Timely Identified or Managed or for Which a Covered Person Fails to Comply with a Management Plan**

If the University identifies a PHS Significant Financial Interest that was not timely disclosed by a Covered Person or was not previously reviewed by the University during an ongoing PHS-funded research project (such as, for instance, a PHS Significant Financial Interest that was not timely reviewed or reported by a subrecipient), the designated University official(s) must, within 60 days of such identification, determine whether a PHS Financial Conflict of Interest exists and, if so, implement on at least an interim basis a management plan that specifies the actions that have been and will be taken to manage the PHS Financial Conflict of Interest.

In all such cases and in situations in which a Covered Person has failed to comply with a management plan, the University must, within 120 days of the University's determination of non-compliance, complete a retrospective review of the Covered Person's activities and the PHS-funded project to determine whether the PHS-funded research, or any portion thereof, conducted during the time period of noncompliance was biased in the design, conduct, or reporting of such research and document the retrospective review. The documentation must include at a minimum

1. The project number;
2. The project title;
3. The Project Director or Principal Investigator (or contact Project Director or contact Principal Investigator if a multiple Project Director/Principal Investigator model is used);
4. The name of the Covered Person with the PHS Financial Conflict of Interest;
5. The name of the entity with which the Covered Person has a PHS Financial Conflict of Interest;
6. The reason(s) for the retrospective review;
7. The detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
8. Findings of the review; and
9. Conclusions of the review.

Based on the results of the retrospective review, if appropriate, the University will update the previously submitted PHS Financial Conflict of Interest report specifying actions that will be taken to manage the PHS Financial Conflict of Interest going forward. If bias is found, the University must notify the PHS awarding component and submit a mitigation report to the PHS awarding component. The mitigation report must include at a minimum:

1. The key elements documented in the retrospective review;
2. A description of the impact of the bias on the research project;
3. The University's plan of action(s) to be taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project);
4. The extent of harm done, including any qualitative or quantitative data to support any actual or future harm; and
5. Analysis of whether the research project is salvageable.

### **I. Special Remedies for Specific PHS-funded Research Projects**

If the Department of Health and Human Services determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by a Covered Person with a PHS Financial Conflict of Interest that was not managed or reported by the University as required by PHS regulations, the University must require the Covered Person to disclose the PHS Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

## **VI. Policy Breaches; Reporting Obligations**



All University faculty and staff members are responsible for reporting to the Provost any known or suspected breach of this policy, including: (a) failure to comply with the conflict evaluation process (by refusal to respond, by responding knowingly with incomplete or inaccurate information, or otherwise); (b) failure to remedy conflicts; and (c) failure to comply with a prescribed monitoring plan. The Provost or his/her delegate will review all such reports. Such cases may be forwarded by the Provost to the Standing Committee on Conflicts of Interest and Commitment for review and recommendations. Based on its review, the Committee will make recommendations to the Provost. If the Provost determines that a conflict of interest exists, the Dean or equivalent, working in conjunction with the Provost and the Covered Person's Department Head, shall design, document, and implement an appropriate management plan.

If a Covered Person's failure to comply with University Policy 101.24 and these Procedures has biased the design, conduct, or reporting of NSF funded research, the Provost is responsible for taking appropriate action to address the matter within the University and for promptly notifying the awarding agency of corrective action taken or to be taken.

## **VII. Appeals**

Any Covered Person has the right to appeal any decision under University Policy 101.24 and/or these Procedures involving that individual to the appropriate Vice Chancellor. Subsequent to any decision by the Vice Chancellor regarding a management plan, any Covered Person who is also a University faculty member may institute the grievance procedures set forth in Section 607(3) of the Code of the University of North Carolina.

## **VIII. Definitions**

As used in University Policy 101.24 and these Procedures, the following terms have the definitions indicated:

1. "COI Manager" means the person charged with responsibility for reviewing all Conflict Evaluation Forms, making the initial determination as to the existence of an actual Conflict of Interest, working with the relevant Dean or equivalent to determine an appropriate management plan for each such a Conflict of Interest, maintaining records of all such Conflicts of Interest and Management Plans, and responding to requests for information from funding agencies and/or from the public regarding Conflicts of Interest.
2. "Covered Person" means:
  - a. Any full- or part-time faculty and EPA non-faculty person employed by the University, by any affiliated entity, or by any other agency or unit of the University;
  - b. Any person who is a Principal Investigator or Project Director of any Public Health Service-supported grant: and
  - c. Any person who is designated by a Principal Investigator or Project Director of any Public Health Service-supported grant as being responsible for the design, conduct, or reporting of the Public Health Service-funded research, or who is listed as being senior/key personnel on any grant application or report submitted to the Public Health Service.

Also, the term Covered Person may, under the circumstances described below, include any subcontractor employee, collaborator, or consultant who is responsible for any portion of the design, conduct, or reporting of Public Health Service-funded research performed under a grant to the University regardless of whether that subcontractor employee, collaborator, or consultant is compensated for his or her work or is an employee of the University. If such a subcontractor employee, collaborator, or consultant participates in the PHS-funded research under a subcontract from the University to an organization that represents to the University in writing that has its own PHS-compliant conflict of interest policy, then the subcontractor employee, collaborator, or consultant may fulfill his or her PHS-required obligations of disclosure of financial interests and management of identified conflicts of interest through that organization as outlined in Section V.A of these Procedures, "Subrecipients of PHS-Funded Research Grants."

Otherwise, the subcontractor employee, collaborator, or consultant is deemed to be a Covered Person, is subject to University Policy 101.24 and these Procedures, and must submit the required Conflict Evaluation Form(s) to the Department Head to whom the University's Project Director or Principal Investigator reports.

1. "Department" means a University academic department or any other administrative unit designated by the Chancellor for the purposes of implementing University Policy 101.24 and these Procedures.
2. "Department Head" means the Department Chair or the person with supervisory responsibility for the Covered Person, whether in an academic or non-academic Department.
3. "Designated Official" means the Dean of the Covered Person's college or, for any Covered Person not residing in any college, the appropriate unit head.
4. "Executive Position" refers to any position that includes responsibilities for a material segment of the operation or management of a business, including Board membership.
5. "Financial Interest" means anything of monetary value. It includes any payment for services to the Covered Person other than compensation from the University, such as consulting fees, honoraria, and paid authorships; equity or other ownership interest, such as stock, stock options, or other ownership interests, in a publicly or non-publicly traded entity; or intellectual property rights and interests that actually generate income for the Covered Person or members of his or her Immediate Family. Income from investment vehicles, such as mutual funds or retirement accounts, in which the Covered Person or member of his/her immediate family do not directly control the investment decisions and intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights are excluded from the definition of Financial Interest.
6. The "Immediate Family" of a Covered Person includes his or her spouse and dependent children.
7. "Participate" means to be part of the described activity in any capacity, including but not limited to serving as the Principal Investigator, co-investigator, research collaborator or provider of direct patient care.
8. "PHS Financial Conflict of Interest" means any Public Health Service (PHS) Significant Financial Interest that the University determines is related to a PHS-funded research

project and could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

9. "PHS Significant Financial Interest" is defined as follows:

- a. A Financial Interest consisting of one or more of the following interests of the Covered Person (and/or those of the Covered Person's Immediate Family) that reasonably appears to be related to the Covered Person's University Employment Responsibilities:
  1. With regard to any publicly traded entity, a PHS Significant Financial Interest exists if the value of any remuneration received by the Covered Person or his or her Immediate Family from the entity in the twelve months preceding the disclosure and the value of any equity interest held by the Covered Person or his or her Immediate Family in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
  2. With regard to any non-publicly traded entity, a PHS Significant Financial Interest exists if the value of any remuneration received by the Covered Person or his or her Immediate Family from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Covered Person or his or her Immediate Family holds any equity interest (e.g., stock, stock option, or other ownership interest) in the entity; or
  3. A PHS Significant Financial Interest exists with respect to any intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests by the Covered Person or his or her Immediate Family.
- b. A PHS Significant Financial Interest also exists upon the occurrence of any reimbursed or sponsored travel (i.e., any travel that is paid on behalf of the Covered Person and not reimbursed by the Covered Person regardless of whether the exact monetary value is readily determinable) related to the Covered Person's University Employment Responsibilities.
- c. The term PHS Significant Financial Interest does not include the following types of financial interests:
  1. Salary, royalties, or other remuneration paid by the University to the Covered Person if the Covered Person is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
  2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as neither the Covered Person nor any member of his or her Immediate Family directly controls the investment decisions made in these vehicles;
  3. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an 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 an institution of higher education;
4. Income from service on advisory committees or review panels for a Federal, state, or local government agency, an 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 an institution of higher education; or
  5. Travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute of higher education that is affiliated with an institution of higher education.
10. "Senior/Key Personnel" means the Project Director or Principal Investigator and any other person identified as senior/key personnel by the University in a grant application progress report, or any other report submitted to the PHS by the University.
11. "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); and 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. An equity interest that when aggregated for the Covered Person and that individual's Immediate Family, 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 represent more than a five percent ownership interest in any single entity; or
  - e. Salary, royalties or other payments, including consulting fees, that when aggregated for the Covered Person and his or her Immediate Family over the next twelve months, are not expected to exceed \$10,000.
12. "Technology" means any process, method, product, compound, drug, device, or any diagnostic, medical, or surgical procedure developed using University time, facilities, equipment, or funds whether intended for commercial use or not.
13. "University Employment Responsibilities" means both University Primary Duties and University Secondary Duties.
14. "University Primary Duties" means assigned teaching, scholarship, research, institutional service requirements, administrative duties and other assigned employment duties. For any Covered Employee who is not an employee of the University (such as a subcontractor employee, collaborator, or consultant), the term "University Primary Duties" means those activities for which that person is responsible under the relevant Public Health Service-funded research project.
15. "University Secondary Duties" means professional affiliations and activities traditionally undertaken by Covered Persons outside of the immediate University employment context and include
- a. membership in and service to professional associations and learned societies;

- b. membership on professional review or advisory panels;
- c. presentation of lectures, papers, concerts or exhibits;
- d. participation in seminars and conferences;
- e. review or editing of scholarly publications and books; and
- f. service to accreditation bodies.

Secondary Duties need not entail the receipt of honoraria, remuneration or the reimbursement of expenses. University Secondary Duties demonstrate active participation in a profession are encouraged, provided they do not conflict or interfere with the timely and effective performance of the Covered Person's Primary University Duties or violate any University Policies. For any Covered Employee who is not an employee of the University (such as a subcontractor employee, collaborator, or consultant), the term "University Secondary Duties" means all of that person's activities other than the University Primary Duties that are directly related to those University Primary Duties.

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