Office of Grants, Research, and Sponsored Programs (GRaSP)

Procedures on Federal Financial Conflict of Interest & Non-federal Financial Conflict of Interest Disclosures

PURPOSE & INFORMATION

Principal Investigators (PIs) and Co-Principal Investigators (Co-PIs) are required to complete a conflict-of-interest form for all grant submissions and sponsored projects.

Dependent upon the sponsor, PIs and Co-PIs will complete either the Federal conflict-of-interest (FCOI) form for federal government sponsors or federal pass thru funding or Form 700-U COI (Statement of Economic Interests for Principal Investigators) for state, county and city governmental entities, and private entities.

As part of the proposal routing procedure, completed conflict-of-interest form(s) will be attached to the proposal routing package. Pre-Award staff verifies that the FCOI and 700U COI forms are uploaded to the proposal routing package. Additionally, Pre-Award staff re-verifies these conflict-of-interest forms before submitting the proposal routing package and award documents for transmission to the Post-Award Office.

Thereafter, the Research Compliance Unit works to collect and update conflict-of-interest forms. Pls and Co-Pls are required to complete FCOI disclosure forms on an annual basis or as needed based on disclosure requirements. Pls are required to complete a form 700-U (Statement of Economic Interests for Principal Investigators) before the final acceptance of a contract, grant or gift for a research project from a non-governmental entity, and within 30 days of renewal of funding for such a contract or grant.

The aim is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from Investigator financial conflicts of interest.

For conflict-of-interest disclosure requirements, please review the FCOI or 700U COI forms for further description and directive.

PROCEDURE FOR COLLECTING AND REVIEWING THE FCOI AND 700U COI DISCLOSURES AT THE PRE-AWARD STAGE

As part of the proposal routing procedure, completed conflict of interest form(s) are a part of the proposal routing package. Pre-Award staff ensure that the FCOI and 700U COI forms are completed and uploaded to the proposal routing package. Additionally, Pre-Award staff reviews these conflict-of-interest forms before submitting the proposal routing package and award documents for transmission to the Post-Award Office. In the event that personnel declare a conflict of interest on either form, the Authorized Organizational Representative reviews and/or approves the declaration (FCOIrequires the AOR to approve via signature, the 700U does not). The Authorized Organizational Representative- Director of Sponsored Programs Development will review the disclosure information to ensure completeness.

Information provided in the Disclosures of those Investigators having a Related, Significant Financial Interest and additional supporting documentation shall be forwarded to the Associate Vice President for Grants, Research and

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Sponsored Programs. The AVP for GRaSP will consider whether the financial interests of the Investigator or the Entity could be directly and significantly affected by the proposed sponsored project and whether the financial interest could affect the design, conduct, or reporting of the 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 entity in which the employee has a financial interest, or when the entity is a proposed subcontractor or participant in the project. A significant impact on the financial interest is one that will materially affect the value of the organization, its earnings, or the sale of its products. The AVP for GRaSP will review the information and make a recommendation as to how a conflict-of-interest management plan/risk mitigation plan should be developed.

In the event of an award, the Management/Mitigation plan is prepared by the AVP for GRaSP and reviewed and signed by the PI, the PI's Dean, and the AVP for GRaSP. The plan shall be monitored for compliance on an ongoing basis or as required by the funding agency. A copy of the Management/Mitigation plan is to be kept with the grant records.

PROCEDURE FOR COLLECTING AND REVIEWING THE FCOI and 700U COI DISCLSURES DURING AWARD ADMINISTRATION

The Pre-award staff collects FCOI or 700U disclosure forms before the final acceptance of a contract or grant for a research project during its proposal/award preparation process in transitioning the award to post-award.

Separately, the Research Compliance Unit – Research Compliance Analyst (RCA) collects disclosure forms when there is a change in PI or Co-PI or when a conflict of interest has been identified. The RCA will review all conflict of interest disclosure forms for compliance. The RCA works to collect and update FCOI's for federally funded projects on an annual basis or as needed.

In the event that personnel declare a conflict of interest on the FCOI form or 700U COI, the Authorized organizational Representative will review and/or approves the declaration (FCOI- requires the AOR to approve via signature, the 700U does not). The Authorized Organizational Representative- Director of Sponsored Programs Development will review the disclosure information to ensure completeness.

Afterwards, information provided in the FCOI or COI disclosure of those Investigators having a Related, Significant Financial Interest and additional supporting documentation shall be forwarded to the Associate Vice President for Grants, Research and Sponsored Programs. The AVP for GRaSP will consider whether the financial interests of the Investigator or the Entity could be directly and significantly affected by the proposed sponsored project and whether the financial interest could affect the design, conduct, or reporting of the 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 entity in which the employee has a financial interest, or when the entity is a proposed subcontractor or participant in the project. A significant impact on the financial interest is one that will materially affect the value of the organization, its earnings, or the sale of its products. The AVP for GRaSP will review the information and make a recommendation as to how a conflict-of-interest management plan/risk mitigation plan should be developed.

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The Management/Mitigation plan is prepared by the AVP for GRaSP and reviewed and signed by the PI, the PI's Dean, and the AVP for GRaSP. The plan shall be monitored for compliance on an ongoing basis or as required by the funding agency. A copy of the Management/Mitigation plan is to be kept with the grant records.

Procedures for the Assessment & Management of Conflicts of Interest

Assessment of Conflicts-of-Interest

After a Conflict of Interest (COI) has been reported or identified, more information will be collected from the Investigator and provided to the Associate Vice President of Grants, Research, and Sponsored Programs (AVP for GRaSP) for review. This information along with the signed and completed disclosure form will be used when developing a COI mitigation plan.

There are 3 main categories to evaluate for the likelihood of a conflict of interest: monetary value, relationships, and authority. The AVP will first evaluate the monetary value involved as the greater the monetary value, the greater the risk for a conflict of interest. Second, the nature of the Investigator's relationships and scope of relationships is examined. Lastly, the authority or scope of influence, the level of discretion, and the decisions an Investigator makes is assessed for potential biases. The document will include instructions for updating, renewing, or terminating the COI mitigation plan.

Required Elements of a Conflict-of-Interest Mitigation Plan

The COI mitigation plan shall be designed to be preventative, corrective, fair, and fully transparent. The plan must include, at a minimum, the key elements documented in the review and a description of the impact of the bias on the research project and the plan of action or actions taken to eliminate or mitigate the bias (i.e., impact on the research project).

There are 3 main elements: the primary interest (end/goals & takes precedence), the secondary interest (financial gain, professional advancement, personal achievement, or favors to friends and family or to students and colleagues & these are more quantifiable), and the conflict itself.

Other types of conflicts of interest include conflicts of obligation and conflicts of commitment. A conflict of obligation (two equally legitimate primary interests) arises when an individual or institution has duties that require different actions but only one of these actions can be taken in the given circumstance. Conflicts of commitment can also be between two competing primary interests; however, the concern involves time and effort, (e.g. an investigator conducting research at 2 different universities). Where applicable, the AVP shall determine in advance which one takes precedence.

Records & Reporting

Once the COI mitigation plan has been developed, reviewed, signed, and dated by all parties, a copy will reside with the grant files and a copy will be given to the Investigator. The AVP or Authorized Organization Representative will submit a report to the funding agency where applicable.

NIH Conflict of Interest Policy

NSF Conflict of Interest Policies

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USDA Conflict of Interest Policy