

# *Sponsored Programs Guidance “Cradle to Grave”*



**DIVISION OF AGRICULTURE  
RESEARCH & EXTENSION**

*University of Arkansas System*

## **Financial Conflict of Interest**

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**Summary: Establishes guidelines for what constitutes financial conflict of interest in terms of sponsored programs and associated procedures.**

It is incumbent on all personnel to strive for a high level of public confidence in the activities of the institution. As the personal integrity of each staff member is the keystone for institutional integrity, all staff should avoid conflicts of interest that may appear to compromise their professional judgment. Any potential conflict of interest must be disclosed, as external activities, paid or unpaid, may interfere with the individual's commitment to the institution and potentially tarnish its reputation.

### **Definitions:**

*Investigator:* The principal investigator, co-investigator, research faculty, professional staff, and external collaborators responsible for the design, conduct, or reporting of research or activities, including the spouse and dependent children of that individual.

*Interest:* Any involvement, financial or not, that an investigator, his/her spouse, or dependent children has with an entity that may allow the investigator or entity to reap personal benefit from a project for which funding is received.

*Significant Financial Interest:* Receipt of anything of monetary value including salary or payment for services (consulting fees, gifts, honoraria, etc.); equity interests (stocks, stock options, etc.); or intellectual property rights (patents, copyrights, royalties, etc.).

*Disclosure:* A written statement filed by each investigator for an activity to be funded through a sponsored program which states the nature of any financial interest the investigator, his/her spouse, and/or dependent children has with the funding agency that may result in real or apparent impact on the sponsored activity.

*Conflict of Interest:* As identified in this document, any external interest that impacts, has the potential to impact, or creates the appearance of impacting an investigator's activity related to a sponsored project.

## **Significant Financial Interest Disclosures**

**Identification of Conflict of Interest:** In determining whether a conflict of interest exists, the investigator must keep in mind that the institution has a responsibility to reduce or eliminate all conflicts whether they be real, potential, or merely present the appearance of impropriety. Disclosure of such conflicts protects both the investigator and institution from embarrassing and harmful allegations.

When considering conflicts of interest, investigators must first identify any special requirements delineated in the funding guidelines. Different funders place a different level of emphasis on conflicts of interest, and adhering to each funder's guidelines is imperative. In general, non-governmental funding sources consider the receipt of salaries and payments or holding of equity interest in an entity that may benefit from a project to be conflicts interest. Likewise, a conflict may be created in the event an investigator serves as a director, partner, trustee, or employee of such an entity. Governmental funding sources, on the other hand, employ two tests to determine if a conflict of interest exists:

1. Does an investigator's significant financial interest or situation create a real, potential, or apparent impact on the investigator's responsibility to the project or institution?; and/or,
2. Does an investigator's significant financial interest or situation create a real, potential, or apparent conflict in which an external entity may benefit from the project?

**Areas of Concern:** Conflicts tend to arise when an investigator's activity creates the potential for bias impacting the nature or direction of the funded project. In considering these impacts, a number of potential problem areas must be considered:

1. Research: An investigator's external interest must not bias his/her judgment in the design or evaluation of research.
2. Publication: An investigator's external interest must not delay or inhibit the reporting of results or dissemination of information related to the funded activity.

3. Education: Results of the funded activity must be conveyed to the public without bias and not in an effort to improve the investigator's standing.
4. Appointments and Promotions: Personnel action should never be used to advance an investigator's external interests.
5. Service on committees: Investigators must take care to ensure that service on a committee does not interfere with the funder's requirements.
6. Consulting: An investigator must ensure that any activity related to the sponsored project does not benefit a consulting arrangement or the entity with which the arrangement exists.

**Responsibilities:** In identifying and disclosing conflicts of interest, both the principal investigator and the Office of Sponsored Programs have specific responsibilities. In order to protect the interests of the institution, it is vital that a cooperative relationship exists in which conflicts of interest can be mitigated.

#### *Principal Investigator*

1. Become familiar with conflict of interest definitions and guidelines.
2. Ensure all personnel involved in the project, including external personnel, are aware of guidelines.
3. Assure the Office of Sponsored Programs that all personnel involved in the project have reviewed personal interests to determine if a conflict exists and, if so, that details of the conflict are disclosed in writing.
4. Assume responsibility for reporting any changes that result in a conflict of interest during the course of funding.
5. Agree to abide by the conditions the administration may impose as a result of a review of conflict of interest disclosures.

#### *Office of Sponsored Programs*

1. Provide funder, if required, certification that the institution has attempted to identify, reduce, or eliminate potential conflicts of interest.
2. Report disclosed conflicts of interest to project sponsors.
3. Report changes that may result in conflicts of interest during the course of funding.
4. Maintain records for future reference if questions arise.

**Procedure:** In order to ensure that conflicts of interest are identified and disclosed, the following procedure shall be followed:

1. The Office of Sponsored Program will provide all principal investigators with a copy of this document and be available for consultation as necessary.
2. The principal investigator shall alert other personnel of the need to comply with the guidelines set forth.
3. All personnel involved with determine whether they hold a significant financial interest in an entity that may result in a conflict of interest.
4. If a conflict of interest does exist, written disclosure must be forwarded to the Office of Sponsored Programs prior to the submission of the funding proposal.
5. If no conflict of interest is reported, the principal investigator will notify the Office of Sponsored Programs that the requirements set forth above have been met.
6. The Office of Sponsored Programs will coordinate review of any disclosure statements to determine if they are significant. If significant, the Office of Sponsored Programs will coordinate recommendations for mitigation.
7. The Office of Sponsored Programs will distribute conditions related to significant conflicts of interest prior to the expenditure of funds. Such conditions may include:
  - a. Public disclosure of the conflict of interest.
  - b. Monitoring of the project by independent reviewers.
  - c. Modification to the project plan.
  - d. Disqualification from participation in all or portions of the project.
  - e. Divestiture of significant financial interest that creates the conflict.
  - f. Severance of any relationships that create the conflict.
  - g. Cancellation of the project.

In any event, the administration may determine that the merits and potential benefits of the project outweigh the risks related to a conflict of interest and allow the project to proceed.

8. The principal investigator will notify the Office of Sponsored Programs of changes of status during the course of funding that may impact previously reported conflicts.

### **Special Conditions for Public Health Service Sponsored Grants\***

\*Note: These special conditions do not apply to proposals submitted to the Small Business Innovation Research (SBIR) Program.

For any PHS (Public Health Service – NIH, CDC, HRSA, FDA, SAMHSA, ATSDR, and AHRQ) funding, there are additional requirements, trainings and verifications that must be completed for any awards after August 24, 2012. Specifics for those requirements can be found in the Federal Register notice of the PHS final rule [http://grants.nih.gov/grants/policy/coi/fcoi\\_final\\_rule.pdf](http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf).

### **Mandatory Training**

Under the new guidelines, investigators must undergo training regarding Financial Conflicts of Interest. NIH has developed an online tutorial that can be accessed at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>. Prior to applying for any PHS-related grant, investigators must complete the tutorial and print the Certificate of Completion. This certificate should be included as an attachment to all future PHS grant proposals routed through the Office of Sponsored Programs (OSP). Investigators engaged in projects currently funded by PHS must complete the training and forward the certificate to OSP.

In addition to initial training, additional training will be required when any of the following occur:

1. It has been four (4) years since the investigator's initial training.
2. UACES revises this policy.
3. An investigator is new to UACES.
4. An investigator is found to be in non-compliance with this policy.

### **Special Considerations**

PHS-sponsored grants have more stringent definitions than many other agencies in regard to financial conflicts of interest. For PHS-sponsored proposals, the following definitions apply:

*Financial Conflict of Interest:* A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

*Financial Interest:* Anything of monetary value, whether or not the value is readily ascertainable.

*Investigator:* the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants. *Under PHS definition, the term "investigator" includes the investigator's spouse and dependent children.*

*Significant Financial Interest:* A financial interest consisting of one or more of the following, including those of the investigator's spouse and dependent children, that reasonable appears to be related to the investigator's institutional responsibilities:

1. Publicly-traded entity: Value of any remuneration received in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary; payment for services not defined as salary (i.e., consulting fees, honoraria, paid authorship); equity interest in stocks or stock options; ownership interest as determined through reference to public prices or other reasonable measures of fair market value.
2. Non-Publicly traded entity: Value of remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator, the investigator's spouse, or the investigator's dependent children holds any equity interest.
3. Intellectual Property Rights: Interest in any patent, copyright, etc. upon receipt of income for such rights and interests.
4. Reimbursed or sponsored-travel.

A significant financial interest does not include:

1. Salary, royalties, or other remuneration paid by UACES to the investigator if the investigator is currently employed or otherwise appointed to the institution.
2. Intellectual property rights assigned to UACES and agreements to share those rights.
3. Income from investments provided the investigator does not directly control investment decisions.
4. Income from seminars, teaching, or engagements sponsored by a federal, state, or local agency; an institution of higher

education including an academic teaching hospital; a medical center; or a research institute affiliated with an institution of higher education.

## **Responsibilities**

### **University of Arkansas Cooperative Extension Service:**

In compliance with rules regarding Financial Conflict of Interest under Public Health Service sponsored grants, the University of Arkansas Cooperative Extension Service will:

1. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest and make that policy available via a publicly-accessible website.
2. Inform each investigator of its policy and the investigator's responsibilities regarding disclosure.
3. Make the official federal register rule regarding Financial Conflict of interest available for review.
4. Provide access to mandatory training.
5. Ensure that any sub-recipient of PHS-sponsored funding complies with this policy by incorporating appropriate financial conflict of interest clauses and certifications in written agreements.
6. Provide Financial Conflict of Interest reports for the investigator or sub-recipient to the project sponsor prior to expenditure of funds and within 60 days of any subsequently identified conflict of interest.
7. Post Financial Conflict of Interest disclosures on a publicly-available website prior to expenditure of funds.
8. Designate an institutional official to solicit and review disclosures.
9. Require each investigator to disclose the investigator's significant conflict of interest, including those of his/her spouse and dependent children.
10. Require each investigator to submit an updated disclosure annually during the period of the award or within thirty (30) days of discovering or acquiring a new financial interest.
11. Provide guidelines to determine whether an investigator's significant financial interest is related to PHS-funded research and, if so, whether the interest represents a financial conflict of interest.
12. Take actions necessary to manage any identified financial conflict of interest of any investigator or sub-recipient via development and implementation of a management plan, retrospective review, and/or mitigation report.
13. Maintain records related to reports of financial conflicts of interest for a period of three (3) years from the date of final expenditures.

14. Establish adequate enforcement mechanisms and provide for administration action to ensure employee compliance.
15. Certify in each application that UACES has a policy in place that promotes and enforces investigator and sub-recipient compliance, manages conflicts of interest and provides reports to the project sponsor, and agrees to make information related to any investigator's conflict of interest disclosure, investigation, or management plan upon request.

### **Investigator**

In accordance with this policy, each investigator seeking funds or participating in a PHS-sponsored project will:

1. Complete mandatory training as identified in this policy prior to submitting a proposal for PHS-sponsored funding or, if participating in a currently funded project, complete training upon notification of this policy.
2. Attach a Certificate of Completion of mandatory training to all PHS-sponsored proposals upon routing to the Office of Sponsored Programs.
3. Disclose any significant financial interest in an entity as required and defined by this policy and federal guidelines.
4. Notify potential sub-recipients of the requirements of this policy during the planning stages of the project.
5. Disclose any subsequently found or acquired significant financial interest within thirty (30) days of discovery.
6. Cooperate fully with any investigation into potential financial conflicts of interest and participate in the development of management plans, mitigation plans, or retrospective reviews.
7. Ensure that, when disclosing significant financial interests, those interests of the investigator's spouse and dependent children are included.
8. Disclose any reimbursed or sponsored-travel provided by an entity, such disclosure to include: the purpose of the trip, the identity of the sponsor, the destination, and the duration. If determined necessary, disclosure of monetary value of travel will be required.

### **Management of Conflicts of Interest**

In the event an investigator discloses a significant financial interest in an entity that is determined to result in a financial conflict of interest, a variety of actions and remedies may be taken. These may include, but are not limited to:

1. Management Plan



- a. Public disclosure within published research reports.
  - b. Disclosure to any participants involved in the research.
  - c. Appointment of an independent monitor to protect the design, conduct, and reporting of research.
  - d. Modification of the research plan.
  - e. Change of personnel or responsibilities related to the research.
  - f. Reduction or elimination of financial conflict of interest.
  - g. Severance of relationships that create financial conflicts.
2. Retrospective Review
    - a. In the event UACES determines that an investigator has failed to comply with this policy it will, within 120 days complete a retrospective review to determine if any design, conduct, or report was biased. The retrospective review will be documented.
    - b. Based on findings, UACES will update the Financial Conflict of Interest report and specify actions that will be taken to manage the conflict in the future.
    - c. If bias is found, UACES will notify the project sponsor and submit a mitigation report to include key elements of discovery in the retrospective review, a description of the impact of bias on the project, and the plan of action taken to eliminate or mitigate the bias.
  3. Mitigation Plan
    - a. In the event bias is found, UACES and the investigator will develop a plan of action to eliminate or mitigate the bias.

## **Remedies**

If an investigator's failure to comply with this policy appears to have created bias, UACES will notify the project sponsor of corrective action. The sponsor will take appropriate action which may include providing directions on how to maintain objectivity.

The sponsor may inquire at any time before, during, or after the award in regard to the investigator's potential conflict of interest. The sponsor may decide that a Financial Conflict of Interest will result in bias and instill additional corrective actions including suspension of funding.

If a Financial Conflict of Interest related to research involving a drug, medical device, or treatment is later discovered, the investigator shall be required to disclose the conflict in all future public presentations and request an addendum to presentation already completed.