



## Office of Research Integrity/Office of Faculty Affairs

# Guidelines for Review of Significant Financial Interest Disclosures

### Role of the Committee

UNLV's Conflict of Interest Rules and Procedures authorize the Conflict of Interest Committee (COIC) to implement two broad functions:

1. Review of Significant Financial Interests (SFI) disclosed by federally funded Investigators; and
2. Serve as a "review committee," as delegated by the appropriate vice president ([NSHE Board of Regents Handbook Title 4, Chapter 3, Section 9.8](#)), to hear appeals of supervisor denials of faculty requests to engage in Compensated Outside Services.

### Definitions

1. Financial Conflict of Interest (FCOI): A significant financial interest that could directly and significantly affect the design, conduct, or reporting of funded research or affect the performance of duties for or by any University employee.
2. Financial Interest: 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, trademarks, copyrights and royalties from such rights), whether or not the value is readily ascertainable.
3. Significant Financial Interest (SFI): A financial interest consisting of one or more of the following interests of the Investigator (or those of the Investigator's spouse or dependent children) that reasonably appears to be related to the Investigator's University responsibilities:
  - (i) Publicly traded entities: a significant financial interest exists if the value of any remuneration received from the entity 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. 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;

- (ii) Non-publicly traded entities: a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or
- (iv) Reimbursed or sponsored travel (i.e., paid on behalf of the Investigator) related to their University responsibilities. This does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, or a U.S. institution of higher education.

Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., paid on behalf of the Investigator) related to their University responsibilities; however, this disclosure requirement does not apply to 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 that is affiliated with an institution of higher education. This disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The University official(s) will determine if further information is needed, including a determination or disclosure of monetary value, to determine whether the travel constitutes an FCOI with the PHS-funded research.

The term *Significant Financial Interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by UNLV to the Investigator if the Investigator is currently employed or otherwise appointed by UNLV, including intellectual property rights assigned to UNLV and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles. All significant financial interests must be evaluated by UNLV to determine whether or not they pose a financial conflict of interest.

## **Federal Regulations**

NSF's conflict of interest policy is outlined in the Proposal and Award Policies and Procedures Guide (PAPPG)<sup>1</sup>. The financial threshold for disclosure is \$10,000 when aggregated for an Investigator and the Investigator's spouse and dependent children during the prior twelve-month period.

The Department of Health and Human Services issued updated regulations that came into

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<sup>1</sup> [https://www.nsf.gov/publications/pub\\_summ.jsp?ods\\_key=papp](https://www.nsf.gov/publications/pub_summ.jsp?ods_key=papp)

effect on August 25, 2011 (42 CFR Part 50 subpart F – Promoting Objectivity in Research).<sup>2</sup> Changes to the Public Health Services conflict of interest policy included:

1. Lower financial disclosure threshold (from \$10,000 to \$5,000).
2. Disclosure of additional information (details about financial interests; the aggregate amount of compensation received from each entity; increased transparency for travel reimbursement). New financial interests must be disclosed within 30 calendar days of obtaining the financial interest.
3. Institutional responsibility for determining if the Significant Financial Interest (SFI) is related to the PHS-funded research, and if so, whether the SFI is a Financial Conflict of Interest (FCOI).
4. New public accessibility requirements regarding Investigators' Conflicts of Interest. FCOI are now posted on university's websites and include the Investigator's name, project, amount of the SFI, and the name of the entity where the financial interest is held.

### **Conflict of Interest Committee (COIC) Review**

The Outside Activity Request Form is completed by all University employees **prior to** beginning any compensated outside service, unless it falls under the [Guidelines for Pre-Approved Activities List](#). These are reviewed by the supervisor/department chair, and the unit head/dean. Outside Activity Request Forms come to the COIC for review in one of three ways:

1. An Outside Activity Request Form stemming from a federally funded Investigator in which the amount of compensation is greater than \$5,000;
2. The unit head/dean believes that a conflict of interest or commitment exists and attempts to negotiate a management plan with the employee have failed; and/or,
3. An employee's Outside Activity Request Form is denied and an appeal is requested.

### **Significant Financial Interest Review Issues**

The purpose of the review is to determine if the investigator's Significant Financial Interest (SFI) is related to the funded research and if so, whether a Financial Conflict of Interest (FCOI) exists. This determination and a response to the employee must occur within 60 days of receipt of the disclosure. Implementation of a management plan, if needed, must also occur within 60 days of receipt of the disclosure.

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<sup>2</sup> <https://www.federalregister.gov/documents/2011/08/25/2011-21633/responsibility-of-applicants-for-promoting-objectivity-in-research-for-which-public-health-service>

An SFI is related to funded research when the COIC reasonably determines that the SFI could be affected by the funded research, or if the SFI is in an entity whose financial interests could be affected by the research.

The following issues should be considered when determining the level of conflict and the value of the research project. This list is not intended to be all-inclusive.

*Conflict of Interest is within acceptable guidelines*

- Ownership interest in sponsor or outside entity is not significant
- Consulting is within guidelines for outside activities
- Consulting is in an area separate from the research project
- Personal consulting agreement terms do not interfere with University obligations
- The Investigator does not stand to benefit financially from the conduct or outcome of this project

*Research is appropriate*

- No product or testing of a product is involved in the project
- Project appears to support research leading to the advancement of knowledge
- Project provides appropriate research activity for students or post-doctoral researchers, and their academic and scholarly interests can be maintained
- Will the research plan receive independent peer review prior to its initiation? If so, by whom and does this reduce potential conflicts?

*Teaching and research environment is open and free of bias*

- The project provides appropriate research activity for students, and students' best interests can be maintained
- No restrictions on the free exchange of ideas, information, or materials are apparent
- Personnel of the sponsor or outside entity will collaborate in the project, but their involvement will not interfere with the appropriate openness of the project
- If any proprietary information of the sponsor or outside entity is provided, restrictions on disclosure of use of such information will not interfere with the openness of the research or dissemination of results
- Are there adequate mechanisms in place to prevent the introduction of bias into the project?  
Are there means provided or available for independent verification of research results?

*Freedom to publish and disseminate results*

- There are no restrictions on the free exchange of ideas, information, or materials
- Personnel of the sponsor or outside entity will collaborate in the project, but their involvement will not interfere with the dissemination of results of the project
- If any proprietary information of the sponsor or outside entity is provided, restrictions on disclosure of use of such information will not interfere with the openness of the research or dissemination of results

- Results will be shared openly with independent researchers and published in peer-reviewed journals

University facilities and resources are used appropriately and are adequately compensated

As is currently the policy, University resources—supplies, equipment, services, and facilities, as well as staff time—must not be used for the benefit of private interests without proper compensation to the University.

- Proposed budget includes appropriate reimbursement of University costs
- Any proposed University cost sharing is consistent with policy and does not favor the sponsor or any outside entity

Intellectual property and technology transfer

- Proposed mechanisms of technology transfer of inventions and copyrights are appropriate
- There is no conflict between University patent and copyright policy and the terms of any consulting or other agreement with the sponsor or outside entity

During the review, the COIC may find it necessary to obtain additional information from the Investigator. Some questions that might be considered when appropriate are:

1. Do the facts and circumstances suggest that the Investigator's financial involvement with the entity will in any way affect or impair the conduct of the research in accordance with the applicable policies and the highest professional standards?
2. How will the interests of the University be maintained in consideration of the Investigator's interest in the entity?
3. Will the research project lead to the advancement of knowledge rather than to routine testing of primary benefit to the entity?
4. How will this research project contribute to the University's mission of teaching, research, and public service?
5. Do the potential public benefits to be gained from undertaking this research outweigh any potential erosion of academic freedom, collegiality, or public trust?

## **Management or Elimination of Conflict of Interest**

In the event of a determination of a FCOI, the COIC will make recommendations for a management plan, which is a course of action to manage, mitigate, or alleviate the conflict of interest.

Management or elimination of conflicts of interest may include but are not limited to:

- Withdrawal of proposal
- Non-acceptance of the gift or grant
- Notice to students and project personnel of the Investigator's conflicting interests
- Appointment of additional, non-conflicted student advisors
- Public disclosure of the related financial interest

- Monitoring of the project by independent reviewers
- Modification of the research or project plan
- Disqualification from participation in all or a portion of the project
- Divestiture of the related financial interest(s)
- Severance of relationships that create actual or potential conflicts

For federally funded investigators, the management plan at a minimum will describe the role and principal duties of the conflicted Investigator in the research project; the conditions of the management plan; how the management plan is designed to safeguard objectivity in the research project; confirmation of the Investigator's agreement to the management plan through signature; how the management plan will be monitored to ensure Investigator compliance; and other information, as needed. This management plan must be forwarded to the designated official for review and approval, disapproval, or further development of management strategies.

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Reviewed by General Council*