

AP-RE-08.2 **Policy No:**

TITLE: **Research Conflict of Interest**

EFFECTIVE DATE: March 10, 2009

CANCELLATION:

ADMINISTERED BY: Office of Research and

Economic Development

REVIEW DATE: Fall 2018

PURPOSE

This Policy applies to all faculty, staff and students involved in Sponsored Research at the University of New Orleans ("UNO" or "University").

These guidelines set forth the Office of Research and Sponsored Programs ("ORSP") policy and procedures governing the identification and management of conflicts of interest that could improperly influence, or create the appearance of improperly influencing, Sponsored Research at UNO. The primary purpose of this Policy is to protect the credibility and integrity of the University and its faculty, staff and students. In doing so, the University may ensure continued public confidence in the University's sponsored activities.

To that end, the University requires that Investigators disclose any Financial Interest or Outside Activity that may present an actual or apparent Conflict of Interest in relationship to Sponsored Research. While most actual or apparent conflicts can be effectively managed, disclosure in accordance with these guidelines is an essential first step in the process.

AUTHORITY

Part Two, Chapter III, Section IV of the bylaws and rules of the University of Louisiana System.

DEFINITIONS

- 1. A Conflict of Interest may arise when an Investigator, a member of an Investigator's family, or an entity with which an Investigator is associated: has an existing or potential financial or other external interest that impairs, or might reasonably appear to impair, the Investigator's independence of judgment in the discharge of his or her professional responsibilities to the University, (for example, when an Investigator or a member of an Investigator's family has a financial or other interest in an entity that supplies or receives funds, goods or services to or from the University), or when the Investigator, a member of the Investigator's family or an entity with which the Investigator is associated may receive a material, financial or other benefit from the use or disclosure of information confidential to the University.
- 2. The Conflict of Interest Review Committee ("CIRC") shall be responsible for the review and resolution of Conflict of Interest issues that may arise in connection with Sponsored Research.

The CIRC shall be composed of the Director for Research and Economic Development, *ex officio*, the Facility Security Officer, the Executive Assistant to the President and the Policy Committee representative from the Principal Investigator's home college and one Policy Committee representative from another college to be selected on a rotating basis.

- 3. **Consulting** means any professional activity related to an Investigator's field or discipline, where a fee-for-service or equivalent relationship exists between a University employee and a third party.
- 4. A **Financial Interest** is any interest in or relationship with an entity including, but not limited to, ownership of stocks, bonds, stock options, partnership or other equity interests, rights to patents or royalty payments, receipt of consulting fees, speaking fees, salary, loans, gifts, lectureship fees, compensation for serving on boards of directors, scientific or other advisory boards, or other remuneration. Note: this does not include stock owned through mutual funds which are not directly managed by the investigator.
- 5. **Intellectual Property** is defined as any legally protected work of the mind (such as technology, software, or scholarly or artistic works), including inventions, plants, mask works, copyrightable works, trademarks, and trade secrets. Intellectual property includes, but is not limited to, commercializable biomaterials, such as transgenic animals or cells and viruses.
- 6. **Investigator** is any UNO individual (including faculty, staff, post docs, graduate assistants and students) who is responsible for the design, conduct, or reporting of Sponsored Research or for the proposal of such Sponsored Research. For the purpose of this Policy, the term includes the following members of the Investigator's immediate family: children, spouses of children, siblings, spouses of siblings, parents, spouse and spouse's parents.
- 7. Outside Activity includes leadership participation in professional, community, or charitable activities, any self-employment, any participation in business partnerships, or any employment or consulting arrangements with entities other than UNO. Outside Activity may be either compensated or uncompensated. In general, any service on any board, whether for-profit, non-profit, advisory, honorary, or otherwise, will constitute an Outside Activity.
- 8. **Sponsored Research** means research, training and instructional projects involving funds, materials, or other compensation from outside sources under agreements which contain any of the following.
 - a. The agreement binds the University to a line of scholarly or scientific inquiry specified to a substantial level of detail. Such specificity may be indicated by a plan, by the stipulation of requirements for orderly testing or validation of particular approaches, or by the designation of performance targets.
 - b. A line-item budget is involved or fixed price contract is involved.
 - c. Financial reports are required.

- d. The award is subject to external audit.
- e. Unexpected funds must be returned to the Sponsor at the conclusion of the project.
- f. The agreement provides for the disposition of either tangible or tangible properties which may result from the activity. Tangible properties include equipment, records, technical reports, theses or dissertations. Intangible properties include rights in data, copyrights or inventions.

GENERAL POLICY

Guidelines for Disclosure

Disclosure is a key factor in protecting one's reputation and career, as well as the University, from potentially embarrassing or harmful allegations of research misconduct. Therefore, each Investigator is required to disclose any Financial Interest or Outside Activity that is directly and significantly related to the research or educational activities funded, or proposed for funding, by an external Sponsor.

Note that these disclosure requirements are "project specific", that is, only Financial Interests and Outside Activities related to the particular research proposal under consideration need be disclosed.

Categories of Potential Conflicts of Interest

Activities that may involve Conflicts of Interest fall into three general categories: first, activities that do not create a conflict and need not be reported; second, activities that are questionable and must be reported, but that may be permitted with administrative approval; and third, activities that are generally not allowable. The following examples are merely illustrative and do not purport to include all possible situations within the three categories listed below.

1. Allowable activities, no reporting required

The examples cited reflect activities external to University employment that may have to be reported pursuant to <u>AP-OP-25.2</u>, <u>Disclosure of Outside Employment</u>, but that do not give rise to a conflict of interest and, thus, need not be reported under *this* Policy.

- a. Licensure of patented inventions subject to the UNO Patent and Copyright Policies (but not licensed by the company/entity sponsoring the research),
- A University employee holding an equity interest in a corporation the exclusive function of which is to accommodate the Investigator's external consulting activities and such company is not funding the Sponsored Research,
- c. A University employee receiving nominal compensation, in the form of honoraria or expense reimbursement, in connection with service to professional associations, service on review panels, presentation of scholarly works, and participation in

accreditation efforts.

2. Activities requiring disclosure for administrative review

The examples cited suggest a possibility of conflicting loyalties that can impair an employee's objectivity, but disclosure and resulting analysis of the relationship may render the activity permissible, perhaps with certain types of limitation or monitoring.

- a. An Investigator or an Investigator's immediate family member serving on the board of directors or scientific advisory board of an enterprise that provides financial support for University research, where the Investigator or an Investigator's immediate family member may receive such financial support,
- An Investigator or an Investigator's immediate family serving in an executive position for a for-profit or not-for-profit business which conducts research or other activities in an area related to the University duties of the Investigator,
- c. An Investigator or an Investigator's immediate family having a financial interest in a for-profit business which conducts research or other activities in an area related to the employee's University duties.

3. Activities or relationships that generally are not allowable

The examples cited reflect activities that are usually not permissible because they involve potential Conflicts of Interest or present obvious opportunities or inducements to favor personal interests over institutional interests. Before proceeding with such an endeavor, a faculty member would have to demonstrate that his or her objectivity would not be affected and/or that University interests would not otherwise be compromised.

- a. An Investigator seeking to enter into a research subcontract with a company with which the Investigator or a member of the Investigator's immediate family has a consulting relationship, has an ownership interest, or holds an executive position,
- **b.** An Investigator participating in University research which is funded by a grant or contract from a company in which the Investigator or a member of the Investigator's immediate family has an ownership interest,
- c. An Investigator assigning students, post-doctoral fellow or other trainees to University research projects sponsored by a business in which the Investigator or a member of the Investigator's immediate family has an ownership interest.

Subrecipients, Subcontractors and Academic Collaborators

Sub-recipients, subcontractors or academic collaborators seeking to contract with the University shall be required to provide assurances that the entity or individual is in compliance with all state and federal laws governing Conflicts of Interest.

Reporting

In accordance with federal regulations, the University will report interests identified as conflicting to the federal granting agency prior to expending any grant funds. The University is also required to report to the federal granting agency within 60 days any conflict identified during the pendency of a federal award. Under certain circumstances, the University may be called upon to provide additional information to granting agencies regarding Conflicts of Interest. Investigators are required to cooperate with the University in complying with such reporting obligations.

Record Retention

Records obtained pursuant to this Policy shall be retained by ORSP for a period of three (3) years following the termination or completion of the award to which they relate or the resolution of any government action involving those records, whichever is later.

Penalties

Violation of federal regulations governing Conflicts of Interest have the potential to jeopardize research funding for the entire University. This Policy is promulgated in order to ensure that such violations do not occur. Failure to comply with this Policy, or with the terms of a Memorandum of Understanding ("MOU") entered into pursuant to this Policy, may result in withdrawal of University support for Sponsored Research and/or disciplinary action in accordance with the Research Misconduct Policy.

PROCEDURE

Investigators are required to disclose all potential Conflicts of Interest to the University **when a research proposal is routed for approval** and must update such disclosures if circumstances change during the period of the award.

The minimum requirements for disclosure include a completed Investigator Disclosure Form ("Disclosure Form") and all supporting documentation, as well as a copy of the proposal. (https://sharepoint.uno.edu/research/coi). AP-OP-25.2, Disclosure of Outside Employment disclosures related to the proposal should be included as supporting documentation. A prior AP-OP-25.2 disclosure does not constitute a disclosure for purposes of this Policy.

Each Investigator who has a Financial Interest or Outside Activity requiring disclosure must complete a Disclosure Form and attach all supporting documentation. These materials must be submitted in accordance with ORSP procedures.

It is the Principal Investigator's responsibility to ensure that each Investigator has read and has complied with the disclosure requirement. The Principal Investigator is further responsible for informing Investigators assigned to the research project, at any time before its conclusion, of the Investigator's obligation to disclose any relevant Financial Interests or Outside Activities in accordance with this Policy.

In the event that an award is offered without a proposal having been routed through the normal

ORSP channels, a Proposal Routing Form, complete with any required disclosures and supporting documentation must be submitted, and all actual or apparent Conflicts of Interest addressed in accordance with this Policy, *prior to acceptance of the award*.

The Director for Research and Economic Development, or their designee, will also conduct a preliminary review of all disclosures to determine whether the matter should be referred to the CIRC for further consideration. The CIRC may make any inquiries, including requests for additional documentation that it considers necessary to make a determination as to whether an actual or apparent conflict exists. The Investigator will be informed of any matters referred to the CIRC.

The University will report Conflicts of Interest that arise in connection with Sponsored Research in accordance with federal regulations, and as required by the granting agency. Under certain circumstances, the CIRC may also determine that the University's interests are best served by informing the Principal Investigator of a potential conflict of a Co-Investigator. In all such cases, the Investigator will be informed prior to any such disclosure and the CIRC will be guided by the principle that disclosures will be strictly limited to information required to protect the University's interests.

Seeking Resolution

The CIRC will review the disclosures and render a decision as to: (a) whether there is an actual or apparent Conflict of Interest within the meaning of this Policy and (b) whether and how the conflict may be managed or resolved.

If the CIRC determines that the actual or apparent conflict can be resolved, the CIRC will work with the Investigator to develop a Resolution Plan. The Resolution Plan shall detail measures to manage, reduce or eliminate any actual or apparent Conflict of Interest. The Resolution Plan may include, but is not necessarily limited, to the following elements.

- 1. Public disclosure of the Financial Interest or Outside Activity,
- 2. Technical review of the research project to be conducted by a faculty panel, independent of the CIRC,
- 3. Development of a plan for monitoring and reporting research outcomes by a panel of experts (internal or external, as the circumstances demand) in the particular field of research, independent of the CIRC,
- 4. Modification of the research plan,
- 5. Disqualification of the Investigator with the Conflict of Interest from participation in all or a portion of the research,
- 6. Divestiture of significant Financial Interests, and/or
- 7. Severance of relationships with the business enterprise or entity that create actual or potential Conflicts of Interest.

Every effort will be made to resolve or manage actual or apparent Conflicts of Interest. However, in the event that a conflict cannot be managed, reduced or eliminated, a project may not be allowed to proceed.

The CIRC shall forward the Resolution Plan to the Director for Research and Economic Development. The Plan shall include any recommended restrictions or conditions that the CIRC believes necessary to manage actual or apparent Conflicts of Interest.

The Resolution Plan shall be structured in the form of a MOU between the Investigator and the University, and will become final upon completion of the following steps.

- 1. Once agreement has been reached on the terms, the MOU will be forwarded to the Department Chair/Director and the Dean of the affected College who may sign off on the MOU, signifying that each is aware of the potential conflict and the recommended resolution procedure or promptly register in writing any concerns to the CIRC which appear not to have been addressed, and return the MOU to the CIRC for further consideration. If the Investigator is a Department Chair/Director or Dean, the MOU will be forwarded for approval to the next person in the chain of authority.
- 2. Once the terms of the MOU have been finalized, the MOU, signed by the PI, the Department Chair/Director and Dean, will be forwarded to the Director for Research and Economic Development for approval and signature. The MOU will become final upon execution by the President. A copy of the executed agreement will be returned to each of the signatories. The original agreement will be retained by ORSP.
- 3. The Department Chair/Director or Dean of the affected College, will be responsible for monitoring compliance with the terms of the MOU, as appropriate under the particular circumstances. Monitoring responsibilities will be specifically addressed in the MOU. If the Investigator is a Department Chair/Director or Dean, the MOU will be monitored by the next person in the chain of authority.

Randy Moffett Interim President

University of New Orleans

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