



Delaware State University

University Area(s) Responsible: Office of the Provost and Vice President for Academic Affairs; Office of the Vice President for Research; Office of the General Counsel

Policy Number & Name: 2-03: Conflict of Interest Policy (COI) for Researchers

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Revisions: _____

I. Background

Researchers have a tradition of free inquiry and free exchange of ideas, "united in the shared purpose to create knowledge, to critique existing knowledge, and to disseminate knowledge." **Trust, the core ethical value in this issue, is essential in the scientific pursuit of the truth.** A relationship based on trust is necessary with colleagues, the government, the study sponsors and, of course, the public. Objectivity is fundamental to this trust.

Conflicts of interest are intrinsic to the researcher's enterprise. And that is why conflicts of interest are so serious. Not only can a conflict lead to injury or harm to particular study participants but, on a larger scale, a conflict of interest can damage an entire research enterprise by reducing the trust and confidence that people generally have in research.

II. Definition of a Conflict of Interest

A conflict of interest involves the abuse -- actual, apparent, or potential -- of the trust that people have in professionals. The simplest working definition states: A conflict of interest is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity. An apparent conflict of interest is one in which a reasonable person would think that the professional's judgment is likely to be compromised. A potential conflict of interest involves a situation that may develop into an actual conflict of

interest. It is important to note that a conflict of interest exists whether or not decisions are affected by a personal interest; a conflict of interest implies only the potential for bias, not likelihood. It is also important to note that a conflict of interest is not considered misconduct in research, since the definition for misconduct is currently limited to fabrication, falsification, and plagiarism.

There are many varieties of conflicts of interest, and they appear in different settings and across all disciplines. While conflicts of interest apply to a "wide range of behaviors and circumstances," they all involve the use of a person's authority for personal and/or financial gain” 2 Conflicts of interest may involve individuals as well as institutions. Furthermore, individuals, in certain circumstances, may have conflicts occurring on both an individual and an institutional level, as may be seen among members of an Institutional Review Board (IRB).

Conflicts of interest are broadly divided into two categories: intangible, i.e., those involving academic activities and scholarship; and tangible, i.e., **those involving financial relationships**.

III. Conflicts of Interest at the Individual Level

Objectivity is the sine qua non of scientific discovery. But bias in judgment is virtually impossible to eliminate. There are often subtle and not so subtle, pressures that can influence how we perceive and how we act. All research professionals understand the pressures to publish, to get funding, appointments, promotions, and to earn respect from peers.

In an effort to succeed, there are myriad areas where bias can influence judgment and diminish objectivity. A desire to validate a pet theory, overconfidence about a particular concept, overreliance on a belief held by a special group, ruling out data that don't support a hypothesis, and internal or external pressures to get a specific result are all influences that may lead to distortions in objectivity. Any of these biases or pressures may lead to what sociologists call *selective in-attendance*. Your mind-set may cause you to overlook important data or to misperceive critical observations.

Bias can be too subtle to recognize and too difficult to control. It can creep into how research questions are selected and framed, the choice of research design, the selection of research participants, and how the data are collected, analyzed, interpreted, and ultimately published.

Whether you describe the glass as half empty or half full is influenced by what you want your results to look like. Bias can even influence the sharing of the results of the study.

IV. Academic Conflicts of Interest or Intellectual Bias

"Academic scientists have special responsibilities to disseminate knowledge, to maintain academic standards, to critique the current state of knowledge, to synthesize existing knowledge, and to apply knowledge to solve basic and applied problems."² The peer-review system is the benchmark of the scientific process. An **academic conflict of interest** could occur if an individual interferes with the peer-review process for some type of intangible personal gain. For example, bias can cause a reviewer to respond positively to a manuscript because it presents results favoring a method or production in which the reviewer has a personal interest or a reviewer may act to delay the publication of a competitor's manuscript in order to strengthen his or her own chances for publication or funding.

These are intangible interests, and they are indigenous to every researcher. Indeed, the drive for recognition can be overwhelming, particularly when a future position or livelihood depends on these public achievements. These are the sources of "**intellectual bias**" that have long been recognized by the research community but that must also be recognized and addressed by the individual researcher.

V. Purpose

The main objective of this Policy and the federal regulations on which it is based is to provide a reasonable expectation that the design, conduct, and reporting of research through funded grants, sub grants, contracts or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. 42 CFR Part 50 Subpart F. The same principles and rules will apply in instances of non-funded research predicated on an individual's relationship with the University.

Processes

The University shall inform each investigator of the University's policy, the investigator's reporting responsibilities, and the federal regulations that authorizes this policy. Prior to the submission of a proposal, those who would participate in, or direct, a federally sponsored project under the auspices of the University must disclose to the University any significant conflict or financial interests which they or any members of their immediate family have in any commercial enterprise that will in any way participate in the sponsored program or that potentially may be affected by the performance or completion of the proposed sponsored program. Disclosure is accomplished through completion and submission of a "Financial Conflict of Interest Disclosure Form" (Disclosure Form) to the Vice President for Research and Economic Development review. Each Disclosure Form will be reviewed to determine the existence of, or potential for, any financial conflicts of interest.

Definitions

Conflict of Interest is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity (see page 1 for further interpretation).

Investigator means the project director or principal Investigator, co-investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of any funded project, or proposal for such funding. Investigator may include, for example, collaborators or consultants.

Researcher includes the principal investigator and all faculty and research staff members who will have responsibility for the design and conduct of the research as well as the dissemination of its results.

Significant Financial Interest (SFI) refers to 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).

FCOI means Financial Conflict of Interest. *Financial conflicts of interest includes:*

- Income (including salary) consulting payments; honoraria, reimbursement of expenses, royalty payments, dividends, or any other payment or consideration from a simple business entity, public entity, or non-profit entity exceeding \$5,000 during the prior twelve months. Investigators must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to the Investigator's institutional responsibilities. This disclosure shall include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
- Equity (in the form of stock, stock options, real estate or any other investment of ownership interests) in any enterprise. (This does not apply in the case of stock holdings such as diversified or mutual funds where the investigator is unaware of specific stock held).
- In regards to a non-publicly traded entity, an SFI 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.

A position as director, officer, partner, trustee, or member of the board of directors of any business entity.

Any ownership interests in the institution, if institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;

Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;

Income from service on advisory committees or review panels for public or nonprofit entities; intellectual property interest on a patent filed or to be filed by a party other than the University.

Royalties from agreements to share in royalties related to licensed intellectual property rights (intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights are still excluded from the SFI definition.)

Exclusions include:

Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;

Intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;

Any ownership interests in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization

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;

Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined in 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;

Income from service on advisory committees or review panels for a federal, state, or local government agency, or 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.

Senior/Key Personnel means the project director or principal investigator and any other person identified as senior/key personnel by the Institution in the grant application,

progress report, or any other report submitted to federal agencies by the Institution under the regulation.

Immediate Family refers to the researcher's parents, siblings, spouse, children and any equivalent relatives by marriage. It also refers to any individual who resides on a regular basis in the researcher's domicile.

VI. Training Requirements

All funded investigators will have to complete mandatory training prior to engaging in any sponsored projects as of August 24, 2012. DSU mandates that each participant completes the online certification training tutorial and print a certificate for filing with other FCOI disclosure documentation. Re-certification shall occur every four years or immediately, if:

- Institution revises its FCOI policy that affects requirements of Investigators
- An Investigator is new to an Institution
- An Investigator is not in compliance with the policy or management plan.

VII. Disclosure, Review and Monitoring Requirements

Each researcher participating in a sponsored project covered by this policy must disclose whether or not he or she has external affiliations that may constitute a conflict. A disclosure must be completed prior to the expenditure of funds or issuance of a subcontract. Disclosure form(s) are completed by the investigator and forwarded to OSP with the proposal application.

Upon reviewing a COI/FCOI Disclosure Statement, OSP will decide whether a management plan is needed. In reviewing the disclosures, OSP will be guided by the following practices and apply them as may be appropriate:

- a. Assure adherence to relevant University policies such as the Principal Investigator Manual, the Faculty and Staff Handbooks, and other University documents that the Conflict Review Committee (CRC) may deem appropriate.
- b. Consider the nature and extent of the COI/FCOI interest in the relationship of the investigator/family member and the entire organization.
- c. Give special consideration to the terms and conditions of sponsored project agreements that may mitigate or complicate the given situation.
- d. Consult with and obtain additional information from the Investigator/family member as either the CRC or the investigator/family member may feel to be helpful in resolving actual or potential conflicts.
- e. Act in a timely manner so as to not delay unduly the conduct of the sponsored project.
- f. Conclude that the University may take one of the following actions:

- Accept the sponsored project award or expenditure.
- Do not accept the sponsored project award or expenditure.

- Accept the sponsored project subject to suitable modifications in either the sponsored project award document.

Monitoring

OSP will review disclosure forms and work with the CRC when needed. OSP will also request annual disclosure forms on all funded projects.

VIII. Reporting Requirements to Federal Agencies

DSU's policy is to send initial, annual (i.e., ongoing) and revised COI/FCOI reports, including all reporting elements required by the regulation, to the agency for the Institution and its subcontractors, if applicable, as required by the regulation. The Institution will provide COI/FCOI reports under the following conditions:

- Prior to the expenditure of any funds under the award, the institution shall provide the awarding agency a COI/ FCOI report regarding any Investigator's significant conflict of interest found by the Institution. (NOTE: As provided by some agency grant policies, Institutions may, at their own risk, incur pre-award costs. However, the Institution must submit the conflict report to the agency prior to the Institution's expenditure of funds authorized under the award, that is, after the Notice of Award is issued and before the specific amount is charged to the award).
- Within 60 days of identifying a conflict of interest for an Investigator who is newly participating in a project.
- At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) provide the status of the conflict and any changes to the management plan, if applicable, until completion of the project.
- Following a retrospective review to update a previously submitted report, if appropriate.
- Retrospective Review

It is the Institution's policy to complete and document retrospective reviews within 120 days of the Institution's determination of noncompliance for conflicts not disclosed timely or previously. DSU is required by federal regulation to conduct a retrospective review in those cases of non-compliance with the federal regulations. This must be done within 120 days of DSU's determination of non-compliance. DSU will notify the

awarding agency promptly and submit a report to the awarding agency in cases where bias is found. The report will address the impact of the bias on a research project and the actions taken by or to be taken by DSU to eliminate or mitigate the bias.

DSU shall document the retrospective review to include all of the following key elements: (1) Project number; (2) Project title; (3) PD/PI or contact PD/PI if a multiple PD/PI model is used; (4) Name of the Investigator with the COI/FCOI; (5) Name of the entity with which the Investigator has a conflict; (6) Reason(s) for the retrospective review; (7) 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.

IX. Maintenance of Records

The Institution's policy for maintaining COI/FCOI files is for at least 3 years from the date the final expenditures report is submitted to the awarding agency. From other dates specified in 45CFR 74.53(b) and 92.42(b), where applicable.

X. Enforcement Mechanisms and Remedies for Noncompliance

Violations of this policy, such as willful concealment of financial interests, may result in sanctions being imposed upon the violating individual. The Vice President for Research and Economic Development or designee(s) will review allegations of violations and will make recommendations regarding the imposition of sanctions. The Vice President for Research and Economic Development—with input from the CRC—shall make recommendations to the Provost/Vice President of Academic Affairs regarding sanctions. Then, the Provost/Vice President of Academic Affairs will make a recommendation to the President. The decision of the President is final.

The Vice President of Research and Economic Development shall maintain the records pertaining to each disclosure in strict confidence. Access to such records will be limited to the investigator/family member, OSP Staff, the Vice President for Research, Provost/Vice President for Academic Affairs and others who have a legal right to review the records. Certain sponsors, particularly federal agencies, may have requirements that differ from this policy with regard to the timing and frequency of disclosures and other provisions as well. In the case of such discrepancies, the federal requirements will generally prevail.

As earlier stated, it is the University's policy to complete and document retrospective reviews within 120 days of the Institution's determination of noncompliance for conflicts not disclosed timely or previously DSU is required by federal regulation to conduct a retrospective review in those cases of non-compliance with the federal regulations.

A. Sub-recipient Requirements

Subcontractors shall provide appropriate assurances to OSP staff that policies and procedures no less stringent than this policy exist and are enforced prior to submission of research proposals and execution of subcontracts.

OSP shall take reasonable steps to confirm that all investigators employed by subcontractors, contractors, and collaborators participating in research are subject to conflict of interest rules and procedures that are no less stringent than this policy.

Subcontractor agreements mandate that they report identified COIs in a time frame that allows DSU to report identified COIs to the federal agency as required by the regulation.

XI. Public Accessibility Requirements

The COI policy shall be posted on DSU's public website. Also, information will be made available concerning conflicts held by senior/key personnel (as defined by regulation) and publicly accessible prior to the expenditure of funds. Website information shall be managed and updated as follows:

- The information that the Institution posts shall be updated at least annually.
- The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest.
- Update the Web site within 60 days of the Institution's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the funded project that was not previously disclosed.
- If the Institution responds to written requests for the purposes of this subsection, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.
- Remain available for three years from the date the information was most recently updated.

The University reserves the right to amend this policy at any time without prior notice.

References

1. Bradley SG, 2000). *Managing Conflicting Interests*. In: Magrina FL, editor. *Scientific Integrity: An Introductory Text with Cases*. Washington, DC: American Society for Microbiology; 2000, pp. 131-157.
2. Policy of The American Society of Gene Therapy on Financial Conflict of Interest in Clinical Research. 2000. Retrieved 2012 August 22 from <http://www.asgt.org>.
3. Jackson State University, “Financial Conflict of Interest Policy for Researchers”, rev. July, 2012.