Ohio University

Conflict of Interest Guidelines

1. A conflict of interest may be present when the individual’s private interests may interfere, or appear to interfere, with professional obligations to Ohio University. This does not imply any wrongdoing, but disclosure and management are required.
2. Ohio University will maintain an up-to-date, written and enforced policy on conflicts of interest for research and other sponsored activities that is publicly available.
3. Ohio University will inform its investigators of the policy on conflicts of interest for research and other sponsored activities and require training on disclosing, avoiding, and managing conflicts of interest.
	1. This training shall be required of all personnel that are responsible for the design, conduct, or reporting of the research or other sponsored activity.
	2. This training shall be required prior to engaging in research or other sponsored activities and then at least once every four years or whenever substantial revisions to the policy or guidelines occur.
	3. Training will be through the Collaborative Institutional Training Initiative (CITI) and is available on line.
	4. Additional training may also be required if an investigator is new to Ohio University or;
	5. When an investigator is found to not be in compliance with the conflict of interest policy or an established management plan.
4. Ohio University will require disclosure of significant financial interests from all personnel with responsibility for the design, conduct or reporting of the project prior to submission of requests for funding for external research or other sponsored activities (or upon joining an ongoing project) through the LEO system.

"Significant Financial Interest" means an interest of an Investigator or his or her family that reasonably appears to be related to the Investigator's Institutional Responsibilities and meets one of the following:

* Remuneration received from any publicly traded entity during the 12 months preceding the disclosure and the value of any equity in the entity as of the date of the disclosure that, when aggregated, exceeds $5,000;
* Remuneration received from any non-publicly traded entity during the 12 months preceding the disclosure that when aggregated exceeds $5,000;
* Any equity interest in a non-publicly traded entity;
* Intellectual property rights and interests, if the Investigator receives income related to such rights and interests from a source other than Ohio University.

"Significant Financial Interest" does not include:

* Salary, royalties, or other remuneration paid by the University;
* 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, an academic teaching hospital, a medical center or 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, an institution of higher education, an academic teaching hospital, a medical center or research institute that is affiliated with an institution of higher education.

"Institutional Responsibilities" means the services for which an Investigator is compensated by the University. For a member of the faculty, Institutional Responsibilities means teaching, research, and service activities in his or her area of professional expertise. For administrators it means activities that are within the scope of the work for which they are compensated by the university. These can include activities such as research, research consultation, teaching, professional practice, Institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

1. Disclosures of significant financial interests (or covered travel), or a statement that there is nothing to disclose, will be submitted via the LEO research administration system. They will first be forwarded for review to the department and college or administrative unit for comment, including any input on the relation to the investigator’s institutional responsibilities.
2. The disclosure will then be reviewed by the Office of Research Compliance. If no significant financial interest is present, and there are no concerns raised by the department or college or administrative unit, the disclosure will be filed within the LEO system without further review except for PHS funded projects which will route on to the conflict review group.
3. If a significant financial interest is present, or concerns are identified, the disclosure will be reviewed by a conflict review group consisting of representatives from the Office of Legal Affairs, the Vice President for Research and Creative Activity, the Office of Research Compliance, the Office of Research and Sponsored Programs and the Office of Technology Transfer. Additional expertise will be added if warranted. Any member unable to make a decision due to involvement in the disclosure under review, or other reasonable belief that they cannot be objective will recuse themselves from the review.
	1. This review will include, at a minimum, whether there is an appearance of a conflict of interest, evaluation of the integrity of the research, any use of human subjects, and involvement of students or other Ohio University personnel.
	2. The investigator may be asked to attend the meeting in which their disclosure is reviewed, or to provide additional information prior to the meeting. The investigators may also request to attend the meeting in which their disclosure is reviewed.
4. If the significant financial interest is reasonably determined to be such that it could directly and significantly affect the design, conduct, or reporting for a sponsored project a potential conflict of interest will be determined to be present.
5. Where a potential conflict of interest is present, the conflict review group will recommend that a conflict of interest management plan be implemented, or that the conflict of interest be eliminated. That decision will be communicated to the investigator and his or her department/college/administrative unit.
6. In the case of a decision to manage the conflict, Ohio University will take such actions as are necessary, including development and implementation of a written management plan, in cooperation with the investigator, prior to expenditure of any funds. Investigators will be required to acknowledge management plans prior to expending funds.
7. Ohio University will develop management plans for conflicts of interest that contain, at a minimum, the following items:
	1. A description of the role and duties of the investigator with the conflict of interest
	2. Conditions of the management plan
	3. How the management plan will safeguard objectivity in research
	4. Confirmation from the investigator that he or she will abide by the management plan
	5. How the plan will be monitored
	6. Any requirements for public disclosure, including whether disclosure is required on human subject consent forms.
8. Management plans will utilize one or more of the following strategies:
	1. Limiting the role of the investigator
	2. Establishing oversight by a third party
	3. Requiring the investigators to divest themselves of the relationship creating the conflict.
	4. Establishing a strategy to reduce financial interests.
9. In the event the conflict review committee determines that the disclosure cannot be managed the investigator will be asked to withdraw from the research and Ohio University may need to decline acceptance of the award, or terminate the sponsored project.
10. Disclosures must be renewed annually.
11. Any new significant financial interests must be submitted as an amendment within 30 days.
12. If the disclosed relationship ceases to exist the disclosure should be amended by selecting the amendment function and then editing to reflect that the potential conflict of interest no longer exists.
13. Decisions on conflicts of interest may be appealed to the Provost or designee.
14. All persons involved in the handling and review of conflict of interest disclosures will exercise due consideration to protect the confidentiality and privacy of the investigators making disclosures to the extent permitted by law.
15. Ohio University will provide initial and ongoing conflict of interest reports to funding agencies pursuant to their requirements.
16. Ohio University will maintain records relating to disclosures of conflicts of interest and the institutions review of, and response to, such disclosures and any actions taken under the institutions policy on conflicts of interest for at least three years from the date of the final expenditures report on the funded project.
17. Ohio University will collect, at a minimum, the following information for disclosed conflicts of interest:
	1. Identifying information (proposal title, funding agency or internal identification number) for the funded project.
	2. The name(s) of the primary investigators and key personnel on the project
	3. The name of the investigator with the conflict of interest
	4. The nature of the financial interest (equity, consulting fees, travel reimbursement, honorarium, etc.)
	5. The value of the financial interest in the following ranges:
		1. $0-4,999
		2. $5,000-$9,999
		3. $10,000-$19,999
		4. $20,000-$39,999
		5. $40,000-$59,999
		6. $60,000-79,999
		7. $80,000-$99,999
		8. Over $100,000 to the nearest increment of $50,000 OR
		9. A statement that the value cannot readily be determined through public prices or other reasonable measure of fair market value
	6. A description of how the financial interest relates to the funded project and the basis for determining that a conflict of interest exists.
	7. A description of the management plan.
18. For investigators with PHS funding there is a requirement to make public disclosure of some information if the investigator has disclosed a significant financial interest (SFI) that is related to the funded research and it has been determined to be a financial conflict of interest. A financial conflict of interest is a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Sponsored Activities. This requirement includes disclosure of the name of the investigator, the investigator’s title and role with respect to the research project, the name of the entity in which the SFI is held, the nature of the SFI and the approximate dollar value of the SFI. Ohio University will assure public accessibility by responding in writing to requests for this information within 5 business days. Requests should be directed to the Office of Research Compliance.
19. Ohio University will annually review reported conflicts of interest and determine the status and if any changes are required for the management of the conflict of interest.
20. If Ohio University identifies investigators who fail to disclose significant financial interests and/or comply conflicts of interest policy, guidelines and any established management plan it will, within 120 days of the determination of noncompliance, complete a retrospective review of the investigator’s activities with relationship to the funded research to determine if there was bias in the design, conduct or reporting of such research. Reports will be made to funding agencies in accordance with each agency’s requirements.

**EXAMPLES**

CONSULTING

1. Company A sponsors research for Investigator X. The project is focused on performing basic research to develop improved methods for something. **There are no students supported by the project or engaged in the work.** *Investigator X has an ongoing consulting relationship with Company A* in an area **UNRELATED** to the University’s focus in this sponsored project.
	1. This requires disclosure but does not pose significant concerns and the disclosure itself may be sufficient or in some cases require a minimal management scenario.
2. Company A sponsors research for Investigator X. The project is focused on performing basic research to develop improved methods for something. **There are students supported by the project or engaged in the work.** *Investigator X has an ongoing consulting relationship with Company A* in an area **UNRELATED** to the University’s focus in this sponsored project.
	1. This requires disclosure and poses significant concerns that will require a more extensive management scenario up to and including requiring that the Investigator X not serve as the thesis advisor if the focus of the thesis is based on the sponsored research.
3. Company A sponsors research for Investigator X. The project is focused on performing basic research to develop improved methods for something. *Investigator X has an ongoing consulting relationship with Company A* in an area **RELATED** to the University’s focus in this sponsored project.
	1. This situation requires disclosure and poses significant concerns that will require an extensive management plan. In some cases this scenario may not be manageable.

STUDENT INVOLVEMENT

1. Investigator A has covered equity in a company which is providing support for graduate student A. The investigator serves on the thesis committee for graduate student A.
	1. This will require disclosure and a management plan.

SERVING AS AN OFFICER OF A COMPANY

1. Investigator A is the chief scientific officer of a company that is providing support for research under the direction of Investigator B. Investigator A is not involved in the university research AND does not have oversight authority over Investigator B.
	1. This requires disclosure but does not pose significant concerns and the disclosure itself may be sufficient or in some cases require a minimal management scenario.
2. Investigator A is the chief scientific officer of a company that is providing support for research under the direction of Investigator B who is the primary investigator. **The sponsored project provides support for a student for whom Investigator A serves as a thesis advisor**. Investigator A is not involved in the university research AND does not have oversight authority over Investigator B.
	1. This requires disclosure and poses significant concerns. While the research is not under the direction of Investigator A (the advisor), the role of thesis advisor to the student while providing research support from a private company for which the advisor plays a significant role is a potential conflict of interest. This scenario would require evaluation of the role of the advisor in the company and the potential influence on the project. Dependent upon the role of the advisor as the chief scientific officer the management plan may require additional oversight or modification of Investigator A’s role as thesis advisor.
3. Investigator A is the chief scientific officer of a company that is providing support for research under the direction of Investigator B. **Investigator A is involved in the university research**.
	1. This requires disclosure and poses significant concerns that will require a very extensive management scenario that will likely involve appointing a different investigator as PI unless there is significant justification for Investigator A remaining as the PI.

LICENSE AGREEMENTS

1. Investigator A has an ownership interest in a company that wants to license University owned technology invented by Investigator A. There will be no University personnel, services or facilities used for the project.
	1. This requires disclosure and may require some management elements such as assuring that students under Investigator A are not working for the company in any capacity and that appropriate disclosures are made to any students, etc.
2. Investigator A has an ownership interest in a company that wants to license University owned technology invented by Investigator A. The University retains ownership. The company will provide support through the University for Investigator A.
	1. This is requires disclosure and poses significant concerns that will require an extensive management scenario that may involve appointing a different investigator as PI and limiting decision making for investigator A.

TRAVEL

1. Investigator A has been asked to provide the keynote speech at a conference sponsored by an organization or company that is not a governmental agency or an institute of higher education. The topic of the speech is within the area of responsibility for the investigator (e.g. within his or her academic discipline). The travel to the conference, registration at the conference and other items are paid for by the organization or the investigator is reimbursed for expenses related to the travel by other than Ohio University.
	1. This requires disclosure of the sponsor, location, duration and purpose of the travel, and the disclosure itself may be sufficient. In some cases additional information such as the total cost of the travel may be required.
2. Investigator A has been asked to provide the keynote speech at a conference sponsored by an organization or company. The topic of the speech is within the area of responsibility for the investigator (e.g. within his or her academic discipline). The travel to the conference, registration at the conference and other items are paid for the investigator by Ohio University.
	1. This does not require disclosure.

Conflict of Interest Management Guidelines

These are guidelines for the management of disclosures where a potential conflict of interest has been determined to be present.

Conflict Type:

Consulting, speaking engagements with company sponsoring research of the investigator

Minimum Management Strategy:

* Disclosure through the LEO COI process
* Disclosure of the relationship in manuscripts
* Disclosure of the relationship to students involved in the research
* If Human Subject Research is present, disclosure in the consent form

Additional Management Consideration

* If the investigator is consulting or speaking about a company product and that product is involved in the research additional management strategies may be needed
	+ Additional disclosures
	+ Additional oversight

Conflict Type:

Ownership Interest (equity, options, etc.) in company sponsoring the research of the investigator

Minimum Management Strategy:

* Disclosure through the LEO COI process
* Disclosure of the relationship in manuscripts
* Disclosure of the relationship to students
* If Human Subject Research is present, disclosure in the consent form

Additional Management Considerations:

* Elimination of ownership interest
	+ Disclosure in manuscripts for some period of time after elimination may be needed
* If ownership is over 25% and elimination is not an option, strategy to reduce ownership interest to less than 25%
	+ Disclosure of the ownership interest in all publications and to students continues
* Assign a different investigator as PI on the project where possible who is not under the supervision of the person holding the interest

If the investigator also has a management position, is on the scientific advisory board or is on the board of directors:

* Eliminate the position where possible. If no then these considerations,
	+ Require someone else to serve as PI where:
* Assign a different investigator as PI on the project where possible who is not under the supervision of the person holding the interest
* If human subject use is involved then these considerations:
	+ - Do not allow recruitment/enrollment in study
		- No access to identifiable information
		- Disclosure in consent form

Conflict Type:

Funding for training students, postdocs, fellowships, etc. provided to the investigator or his/her department from the company sponsoring the research.

Minimum Management Strategy:

* Disclosure through the LEO COI process
* Disclosure of the relationship in manuscripts
* Disclosure of the relationship to students
* If Human Subject Research is present, disclosure in the consent form

Additional Management Considerations:

* If there are restrictions or stipulations on the funding assure that there is no advantage provided to the company, or disadvantage incurred by the recipients.
* Assure publication rights for students