

VIII. POLICIES ON INDIVIDUAL CONFLICTS OF INTEREST AND INSTITUTIONAL CONFLICTS OF INTEREST

Introduction

This document establishes policies on individual conflicts of interest and institutional conflicts of interest.

Research, scholarship, and other creative endeavors have enormous potential to benefit humankind, and the University strongly supports efforts to bring discoveries to society. The purpose of these policies is to protect the University, its faculty, non-faculty employees, students, and trainees, and human subjects and animals in research, and to comply with applicable federal laws. The policies seek to accomplish this by striking the proper balance between, on the one hand, the goal of preserving academic freedom and encouraging outside scholarly and entrepreneurial activities by members of the University that enhance the prestige and reputation of the University and benefit society, and, on the other hand, the need to preserve the integrity of the University and its members and to fulfill the University's responsibilities to the public. In striking this balance, the interests of the public, the integrity of the University and its individual members, and the safety of research subjects always must be given priority.

These policies apply generally to the members of the Board of Trustees, all University officers, senior officials, faculty (whether or not engaged in research or other scholarly or creative endeavors), volunteer faculty at the School of Medicine engaged in sponsored research, post-doctoral fellows and scholars, non-faculty employees, students, and trainees. The specific policies cover specific types of individuals.

The University Conflict of Interest Committee.

The members of the Conflict of Interest Committee, including the leadership of the committee, are appointed by the President and include faculty, non-faculty employees, and administrators. The Conflict of Interest Committee includes at least one member of the public who serves as a regular member of the Conflict of Interest Committee, and a second member of the public who serves as an alternate member of the Conflict of Interest Committee. The members of the public must not have any affiliation with the University (including as alumni, faculty, clinical faculty, adjunct faculty, or emeritus faculty) or with its affiliated hospitals (other than as patients). To the maximum extent possible, the members of the public must be independent of the line of authority for institutional oversight of research. A majority of the members of the Conflict of Interest Committee are members of the faculty as defined in Article I, sections (A) and (B) of the University Faculty Handbook, and one of these faculty members is appointed by the Executive Committee of the Faculty Senate. Membership also includes representatives from hospitals affiliated with the University. These members only participate in the resolution of conflicts of interest involving research.

Members of the Conflict of Interest Committee must recuse themselves from consideration of their own conflicts of interest, or institutional conflicts of interest that relate to their own conflicts of interest.

I. Individual Conflict of Interest Policy.

A. Who is covered by this policy?

The conflict of interest policy applies to the members of the Board of Trustees; all University officers; senior (“cabinet-level”) officials of the University (comprising the President, Provost, General Counsel, Senior Vice President for Administration, Chief Financial Officer, Vice President for Medical Affairs, the Chief of Staff, the vice presidents for Development, University Relations, and Diversity, Inclusion and Equal Opportunity, and any other individual that the President designates); all University faculty except volunteer faculty in the School of Medicine (unless engaged in sponsored research) and except special faculty members who are not paid by the University, unless engaged in sponsored research; emeritus faculty who have an ongoing relationship with the University or who are engaged in sponsored research; post-doctoral fellows, all employees; students; and trainees. “University faculty” are those individuals defined as University faculty in the Faculty Handbook.

This policy applies to these individuals regardless of where they conduct activities covered by the policy.

B. What is an individual conflict of interest?

An individual conflict of interest exists when an individual covered by this policy has a financial interest that might adversely affect or appear to a reasonable person to adversely affect the individual’s judgment in carrying out University responsibilities, or that might adversely affect or appear to a reasonable person to adversely affect the University’s responsibility to the public, the safety of research subjects, or the integrity of research.

C. Reporting.

The reporting requirements under this policy are broad, in order to provide adequate protection for individuals covered by the policy, the University and affiliated institutions, and the public interest. It is important to recognize that a reporting requirement does not indicate that the activity in question is in any way objectionable; indeed, reporting is required in connection with many activities in which members of University are expected to engage, such as funded research, or that are otherwise praiseworthy, such as the receipt of honorary awards.

1. Who must report?

The following individuals must report under this policy: the members of the Board of Trustees; all University officers and senior officials, as defined in section I(A) of this policy; all University faculty (whether or not engaged in research), except volunteer faculty in the School of Medicine (unless engaged in sponsored research) and except special faculty members who are not paid by the University, unless engaged in sponsored research; emeritus faculty; and senior/key personnel and other individuals who contribute to the scientific development or execution of a research project in a substantive way, and any other employees at the request of their supervisor. Students and post-doctoral fellows and scholars do not have to report unless they contribute to the scientific development or execution of a research project in a substantive way.

2. What activities must be reported?

Individuals covered by this policy must report any financial interest (defined in the attached glossary) and the acceptance of any gifts, favors, or anything of value, by the individual or the individual’s spouse, dependent children, domestic partner, or any other dependent person who is a member of the same household as the individual, that directly or indirectly might influence or appear to a reasonable person to influence the individual’s responsibilities as a member of the University.

Individuals covered by this policy who engage in research must report any financial interest, no matter how small, that the individual or the individual's spouse, dependent children, domestic partner, or any other dependent person living in the same household as the individual, has in any entity that sponsors or supports the research or that holds a financial interest in the subject of the research, and also must report the acceptance of any gift, favor, or anything of value from an entity that sponsors the research or that holds a financial interest in the subject of the research.

Individuals covered by this policy also must report whenever a previously reported conflict of interest is eliminated.

Whenever an individual covered by this policy has any doubt about whether or not an activity must be reported, the individual should report the activity.

3. What activities are permitted without reporting?

Certain activities may be engaged in without reporting. Typically, these are activities not covered in section 2 above in which academics routinely engage and in which an individual's financial interests are not expected to influence the individual's judgment.

Examples of activities in which individuals may engage without reporting include:

Receiving royalties for published scholarly work and other writings.

Accepting reasonable meals and other customary business amenities (such as pads and pens) that are provided as part of a seminar, course, meeting, or other business-related gathering.

Income and travel expenses from service on advisory committees or as a reviewer for governmental and recognized inter-governmental or academic entities or professional societies.

Honoraria for reviewing scholarly manuscripts for publication by academic journals or presses.

Income from diversified mutual funds.

Honoraria and travel support for scholarly presentations to U.S. federal agencies (such as the National Science Foundation, National Institutes of Health, Department of Energy, Department of Defense, National Endowment for the Arts, and National Endowment for the Humanities).

Grants and contracts administered through the University.

Whenever an individual has any doubt about whether or not an activity must be reported, the individual should report the activity.

4. How is reporting to be made and to whom?

The University's reporting process is administered by the University's Conflict of Interest Office, except that reporting by members of the Board of Trustees, the President, the Provost, all senior officials of the University, as well as the Chair of the Conflict of Interest Committee, is administered by the Office of General Counsel, and except that the General Counsel reports to the President. Each year, individuals covered by this policy must report in writing any activities listed above. Reports called for by the Conflict of Interest Committee are submitted to that committee. Reports called for by the Office of General

Counsel are submitted to that office. The reports received by the Conflict of Interest Committee are shared with the deans and department chairs of the reporting faculty.

Individuals covered by this policy who are not required to report to the Conflict of Interest Committee (other than those described in the preceding paragraph who must report to the Office of General Counsel or the President) must report any financial interest that relates to their University responsibilities to their supervisors at their annual review. Supervisors who determine that an individual may have a conflict of interest must report this to the Conflict of Interest Office for further review.

Compliance with this policy does not relieve the individual from complying with IRB or IACUC reporting requirements.

5. When is reporting to be made?

Reporting must occur at least annually as instructed by the Office of General Counsel or the Conflict of Interest Office. Individuals also must report the Conflict of Interest Office or the Office of General Counsel, as appropriate, within 10 days after they become aware of a reportable interest or after a conflict of interest has been eliminated. Individuals who have no reportable interests must still submit an annual report to be in compliance with this policy.

Individuals who have been recruited to the University must report any conflicts of interest sufficiently in advance of their start date that the conflicts can be reviewed and resolved by the Conflict of Interest Committee prior to their start date.

Reporting also is required at the time a research proposal is submitted on the electronic University Review Form, and when a research proposal is submitted to relevant review bodies (such as the CWRU IRB, Cancer IRB, CWRU IACUC, and affiliated IRBs).

As per 42 CFR part 50, the University reports to the NIH a conflict of interest related to NIH research prior to the expenditure of grant funds, and within 60 days of identifying any new conflict of interest. The report to the NIH specifies whether the University will manage, reduce or eliminate the financial conflict of interest.

D. Review and approval.

1. What is the review process?

The Office of General Counsel conducts an initial review of all the reports it receives. The Conflict of Interest Office conducts an initial review of all reports it receives. If necessary, they obtain additional information from the individual covered by the policy and from other individuals who possess relevant information. The Office of the General Counsel or the Conflict of Interest Office, as appropriate, then identifies those activities that must be reviewed and approved by the Conflict of Interest Committee, and those activities that may proceed without review by the Conflict of Interest Committee. The Office of the General Counsel or the Conflict of Interest Office, as appropriate, notifies the Conflict of Interest Committee or the Board of Trustees of those activities that must be reviewed and approved.

2. What is the approval process?

In reviewing a reported activity, the Conflict of Interest Committee assumes that the activity cannot be undertaken without a suitable management plan. However, in some cases, the activity may be approvable

without a management plan. In determining whether a management plan is required, the Conflict of Interest Committee considers the significance of the conflict of interest (such as the size of the individual's financial interest); whether or not the individual is uniquely qualified by virtue of expertise and experience to conduct the research project and the research could not be conducted as safely or effectively without that individual; and the degree of risk imposed on research subjects.

Following are some examples of conflicts of interest. In specific cases, individuals may be able to engage in some of these activities with a suitable management plan:

- a. Serving as an investigator on a research project involving human subjects that is either sponsored by a company or related to the company's products while that faculty member is receiving royalties, consulting fees, or has equity (or stock options or a future "inventor's share") in the same company.
- b. Ghostwriting or having the individual's name attached to a paper written by another individual consulting for or directly employed by industry, including papers featuring data that were simply presented to the individual (without the opportunity to analyze directly, perform calculations, review and/or question the data).
- c. A faculty member directing students to purchase books for a course from a bookstore in which he or she or his or her immediate family have a significant ownership interest.
- d. Managing the renovation of departmental offices and participating in the selection of an architectural firm in which his or her spouse is a partner.
- e. A faculty member acting as a thesis or dissertation advisor to a graduate student for a research project, suggested by the faculty member, that the faculty member expects will substantially enhance the value of a company in which the faculty member has a significant ownership interest.
- f. A professor requiring students currently enrolled in his or her class to participate in his or her graduate student's thesis research project as part of course requirements unless deemed pedagogically justified by the individual's department chair or dean.
- g. A professor requiring students currently enrolled in his or her class to participate in his or her or another professor's research project unless deemed pedagogically justified by the individual's department chair or dean.
- h. A faculty or non-faculty employee with a financial interest in an outside company serving as the direct academic or research supervisor of a university student/trainee who is employed by that company.
- i. A faculty member with a financial interest in an outside company serving as the sole thesis committee chair if the focus of the student's thesis is based on research sponsored by the company.
- j. Issuing a University subcontract for research to an outside entity in which the local principal investigator on the research project has a financial interest.
- k. Receiving research support for human subjects research from industry without a contract, or for more than the reasonable costs of conducting the contracted research.
- l. Accepting financial support directly from external sources, rather than through the university, for research conducted in a University laboratory or utilizing University resources.

- m. Accepting compensation from companies for attending or defraying the costs of an industry-sponsored continuing medical education event (including gifts, travel, or accommodations) if the individual is not speaking or presenting.
- n. Presenting talks or serving on speakers' bureaus that advertise, market or advance industry products, devices or other technologies, including the marketing of off-label drugs.
- o. Receiving payments conditioned upon a particular research result or tied to successful research outcomes.
- p. While serving on a board of directors, participating in human subjects research on a technology owned by or obligated to the business, or receiving sponsored research from the business.
- q. Possessing a financial interest that competes with the services provided by the University.
- r. Taking administrative action within the University that is beneficial to a business in which an individual has a financial interest.
- s. Accepting personal gifts from industry, however small, including for listening to a sales talk by an industry representative, or for prescribing or changing a patient's prescription.
- t. Making referrals to a business in which an individual has a financial interest.

In the case of an individual who is newly hired at the University, the Conflict of Interest Committee may permit a prohibited conflict of interest to continue for a finite period of time during a suitable transition period, provided that the period is as short as possible.

3. Management plan.

The Conflict of Interest Committee may decide to approve an activity subject to a suitable management plan. The management plan may include but is not limited to:

- a. Requiring the individual to recuse him/herself from particular business decisions.
- b. Requiring the individual to inform certain persons or institutions about the conflict of interest and the management plan (such as the Office of Research Compliance, IRBs, IACUCs, subjects, state and federal officials, research sponsors, co-investigators, colleagues, junior colleagues, students, trainees, members and prospective members of the individual's research laboratory, journals to which manuscripts about the research are submitted, and media, lay, and professional audiences with whom the research or other activity is discussed orally or in writing).
- c. Requiring the individual to refrain from participating in certain activities or aspects of activities relating to the research project (such as requiring IRB members with conflicts of interest in connection with research protocols to recuse themselves from deliberations on those protocols, or, where compelling circumstances exist to allow certain research stages or activities to proceed despite a conflict of interest, restricting the individual's roles to those stages and activities, including establishing a point in time for stopping participation and strategies to keep the individual's involvement at a minimum).
- d. Requiring the activity to be approved by additional individuals or entities (such as deans, department chairs, or program chairs).
- e. Requiring others to review academic decisions in which the individual participates.

- f. Requiring independent involvement in the research (such as in recruiting and selecting subjects, participating in or designing the consent process, providing clinical treatment to subjects apart from the research intervention or procedures, monitoring data, reviewing study design, collecting data, and determining authorship status or order).
- g. Requiring the individual to reduce, modify, or eliminate a financial interest (including divesting ownership, restricting the sale or exercise of stock and stock options, and deferring or waiving royalties or milestone payments).
- h. Requiring the individual to vacate a position.
- i. Prohibiting the individual from disclosing confidential institutional information or channeling discoveries to an outside entity.
- j. Prohibiting the research from taking place at the University.
- k. Requiring continued oversight of the activity by the Conflict of Interest Committee.

Management plans are developed according to the nature of the significant financial interest and of the sponsored research--e.g., whether there is an institutional as well as an individual conflict of interest, and whether the investigator is conducting bench, animal or human subjects research.

Before finalizing a management plan, the Conflict of Interest Committee must review the plan with the appropriate dean; in the case of University officers, with the appropriate senior official; and in the case of non-school-based non-faculty employees, with the senior University official with oversight over them. If the dean or senior official and the Conflict of Interest Committee are unable to agree on the terms of the management plan, the matter is referred to the Provost or Senior Vice President for Administration.

E. Appeals.

If an individual covered by this policy who is a faculty member is dissatisfied with a determination of the Conflict of Interest Committee, the individual may submit a written appeal to the Provost within 10 days of receipt of the decision. If the Provost upholds the Conflict of Interest Committee's determination, the Provost's decision is final. If the Provost modifies or overrules the Conflict of Interest Committee's determination, the Conflict of Interest Committee may appeal to the President.

A non-faculty employee who is dissatisfied with a determination of the Conflict of Interest Committee may submit a written appeal to the Senior Vice President for Administration within 10 days of receipt of the decision. If the Senior Vice President for Administration upholds the Conflict of Interest Committee's determination, the decision of the Senior Vice President for Administration is final. If the Senior Vice President for Administration modifies or overrules the Conflict of Interest Committee's determination, the Conflict of Interest Committee may appeal to the President.

If the individual is the President, the President may submit a written appeal to the Audit Committee of the Board of Trustees within 10 days of receipt of the decision.

If the individual is a member of the Board of Trustees, the appeal is conducted in accordance with the policies and procedures of the Board of Trustees.

If, when the Conflict of Interest Committee and the dean or senior official who reviews a management plan are unable to agree on the terms of the plan and the matter is referred to the Provost or Senior Vice President for Administration, the Conflict of Interest Committee or the dean or senior official is dissatisfied with the decision of the Provost or Senior Vice President for Administration, they may refer the matter to the President.

II. Institutional Conflict of Interest Policy.

A. Who is covered by this policy?

This institutional conflict of interest policy applies to the members of the Board of Trustees, the President, the Provost, all senior (“cabinet-level”) officials of the University (comprising the President, Provost, General Counsel, Senior Vice President for Administration, Chief Financial Officer, Vice President for Medical Affairs, the Chief of Staff, the vice presidents for Development, University Relations, and Diversity, and any other individual that the President designates), vice presidents, vice provosts, deputy provosts, deans, associate and vice deans, department chairs, academic division chiefs, directors of department-level centers, IRB chairs, the chair of the Conflict of Interest Committee, the chair of the Institutional Biosafety Committee, and directors of institutes and centers with department-level status.

B. What is an institutional conflict of interest?

An institutional conflict of interest arises when the financial interests of the University, or a University official acting within his or her authority on behalf of the University, may influence or appear to influence the research, education, clinical care, business transactions, or other activities of the University. In the case of research, the concern is that the financial interests of the University, or of a University official acting within his or her authority on behalf of the University, might affect—or reasonably appear to affect—University processes for the conduct, review, or oversight of the research.

An institutional conflict of interest also might arise when an individual covered by this policy receives a financial or other benefit from the use or disclosure of non-public information pertaining to the University.

Institutional conflicts of interest may arise when outside activities are inconsistent with an individual’s responsibilities to the University. Outside activities include leadership participation in professional, community, or charitable activities, self-employment, participation in business partnerships, employment or consulting arrangements with entities other than the University, either compensated or uncompensated, and service on any private-sector board, including for-profit, non-profit, advisory, or honorary. These activities are inconsistent with an individual’s responsibilities to the University when they adversely influence or appear to adversely influence the research, education, clinical care, business transactions, or other activities of the University.

An individual conflict of interest may raise an institutional conflict of interest issue and vice versa.

C. Reporting.

There is no separate individual reporting under the institutional conflict of interest policy. The information reported on individual conflict of interest forms is used in carrying out the institutional conflict of interest policy.

In addition, the Conflict of Interest Office periodically must receive the following information:

1. From the Senior Vice President of Finance and Chief Financial Officer, a list of the entities in which the University has any financial interest.
2. From the Board of Trustees, a list of the entities in which members of the Board of Trustees and senior officials of the University, their spouses, dependent children, domestic partners, or any other dependent person living in the same household as the individual, have any financial interest. The list of entities provided by the Audit Committee of the Board of Trustees to the Conflict of Interest

Committee does not contain the identities of the individuals who have the financial interest in those entities.

3. From the Office of Development, a list of major gifts to the University.
4. From the **Technology Transfer Office**, a list of the University's equity holdings and technology licenses.

D. Review and approval.

1. What is the review process?

Reviews of reports conducted solely by the Audit Committee of the Board of Trustees are conducted according to the rules of the Board of Trustees.

In the case of all other reports, the Conflict of Interest Office conducts an initial review. If necessary, it obtains additional information from the individual covered by the policy and from other individuals who possess relevant information.

The Conflict of Interest Office also reviews potential institutional conflicts of interest that are not required to be reported by an individual, such as non-reportable potential conflicts that the Conflict of Interest Office becomes aware of based on its review of the lists it receives from the Senior Vice President of Finance and Chief Financial Officer, the Board of Trustees, the Office of Development, and the Office of Research and Technology Management.

The Conflict of Interest Office then identifies those activities that must be reviewed and approved by the Conflict of Interest Committee, and those activities that may proceed without review by the Conflict of Interest Committee, and notifies the Conflict of Interest Committee of those activities that the committee must review and approve.

2. What is the approval process?

In reviewing a reported activity, the Conflict of Interest Committee assumes that the activity cannot be undertaken without a suitable management plan. However, in some cases, the activity may be approvable without a management plan. In determining whether a management plan is required, the Conflict of Interest Committee considers the significance of the institutional conflict of interest (such as the size of the individual's financial interest); whether or not there the individual is uniquely qualified by virtue of expertise and experience to conduct the research project and the research could not be conducted as safely or effectively without that individual; and the degree of risk imposed on research subjects.

Following are some examples of institutional conflicts of interest. In specific cases, individuals may be able to engage in some of these activities with a suitable management plan:

- a. Activities in which the University or a University official, acting within his or her authority on behalf of the University, has a financial interest (as defined below) that may adversely affect or appear to a reasonable person to adversely affect the research, education, clinical care, business transactions, or other activities of the University.
- b. Activities in which an individual covered by this policy has a financial interest that directly or indirectly might influence or appear to influence the individual's University responsibilities.
- c. Activities in which an individual covered by this policy receives a financial or other benefit from the use or disclosure of non-public information pertaining to the University.
- d. Outside activities (including leadership participation in professional, community, or charitable activities, self-employment, participation in business partnerships, any employment or consulting

arrangements with entities other than the University, either compensated or uncompensated, and any service on any board, including for-profit, non-profit, advisory, or honorary) that adversely influence or appear to adversely influence the research, education, clinical care, business transactions, or other activities of the University.

- e. Research at the University on human subjects (including serving as the principal investigator or sharing in the responsibility for the design, conduct, or reporting of the research) by individuals covered by this policy who have a financial interest (as defined below), no matter how small, that the individual or the individual's spouse, dependent children, domestic partner, or any other dependent living in the same household as the individual, in any entity that sponsors the research or owns a technology that is the subject of the research.
- f. Research at the University on human subjects or on animals (including serving as the principal investigator or sharing in the responsibility for the design, conduct, or reporting of the research) by individuals covered by this policy who materially participate in a procurement or purchasing decision involving major purchases from, or non-routine supply contracts with, a commercial entity that sponsors the research.

A "financial interest" includes income; honoraria, consulting fees, advisory board fees, membership on a speaker's bureau, remuneration, gifts or other emoluments, "in kind" compensation, equity such as stock, stock options or other ownership interests; royalties; non-university grants; debts; loans; non-university contracts; licensing agreements; inventors' shares; and a board or other position with advisory or fiduciary duties, even if uncompensated.

3. Management plan.

The Conflict of Interest Committee may decide to approve an activity subject to a suitable management plan. The management plan may include:

1. Isolating the individual from involvement in research or decision-making regarding research.
2. Requiring the individual to reduce, modify, defer, waive, or eliminate the financial interest that is the source of the conflict, such as equity holdings, royalty income, stock options and milestone payments.
3. If recusal would preclude the individual from fulfilling the responsibilities of a University position, requiring the individual to eliminate the holdings or vacate the position.
4. Requiring the individual to recuse him- or herself from institutional decisions regarding the outside entity that is source of conflict.
5. Requiring the individual to make periodic written disclosure of the conflict to all administrators, faculty, non-faculty employees, and students under individual's supervision, to the Office of Research Compliance, IRBs, IACUCs, subjects, state and federal officials, research sponsors, co-investigators, colleagues, junior colleagues, students, trainees, members and prospective members of the individual's research laboratory, journals to which manuscripts about the research are submitted, and media, lay, and professional audiences with whom the research or other activity is discussed orally or in writing.
6. Appointing independent individuals or committees to oversee high-level administrative decisions (e.g., financial decisions, space allocations, appointments and promotions) in which the individual participates.
7. Prohibiting the research from taking place at the University.
8. Eliminating, reducing, or modifying the University's financial stake in an outside entity or research project.
9. Enhancing or creating firewalls or other conflict-management systems to separate financial and research decision-making.
10. Requiring independent involvement in the research (such as in recruiting and selecting subjects, participating in or designing the consent process, providing clinical treatment to subjects apart from

the research intervention or procedures, monitoring data, reviewing study design, collecting data, and determining authorship status or order).

11. Preventing the individual from serving as the principal investigator, co-principal investigator, or investigator on the research project.
12. Protecting students, trainees, junior colleagues and/or non-faculty employees by preventing or limiting their participation in the research project, preventing or limiting them from working in newly-formed companies involving conflicted superiors, informing them of the potential conflict, giving them access to senior faculty and non-faculty employees to review questions or concerns, having academic decisions outside the research activity made or reviewed by independent individuals, and recusing the conflicted individual from the chain of authority over salary, promotion, and space allocation decisions.
13. Prohibiting the individual from participating in institutional negotiations with the outside entity except as the University directs.
14. Prohibiting the individual from serving on the board of directors of the outside entity, or as an officer, member of the scientific advisory board, member of a speakers' bureau, or consultant.
15. Prohibiting the individual from disclosing confidential University information.
16. Prohibiting the individual from channeling discoveries to the outside entity.
17. Prohibiting the university from accepting research grants from companies founded by the individual.

Before finalizing a management plan, the Conflict of Interest Committee must seek input from the appropriate University officials

E. Appeals.

When an individual with an institutional conflict of interest also has an individual conflict of interest, the appeal process under the individual conflict of interest policy applies.

In the event that an individual who does not have an individual conflict of interest is dissatisfied with a determination of the Conflict of Interest Committee, the individual may submit a written appeal to the President within 10 days of receipt of the decision. If the individual is the President, the President may submit a written appeal to the Audit Committee of the Board of Trustees within 10 days of receipt of the decision. If the individual is a member of the Audit Committee, the Audit Committee's deliberations and decision is conducted in accordance with the policies and procedures of the Board of Trustees.

If the President or the Audit Committee upholds the Conflict of Interest Committee's determination, the decision is final. If the President modifies or overrules the Conflict of Interest Committee's determination, the Conflict of Interest Committee may appeal to the Audit Committee.

III. Confidentiality

All information contained in reports or obtained in the course of reviewing a potential conflict of interest, institutional conflict of interest, or conflict of commitment, is strictly confidential. The information is only available to the Conflict of Interest Office and the individuals charged with the responsibility for review in the particular case.

IV. Sanctions

Failure to comply with these policies includes failing to submit a required report, providing false information, omitting required information, failing to maintain confidentiality, failure to carry out duties prescribed by these policies, and refusal or failure to comply with a management plan adopted under these policies.

A failure to comply with these policies may, in the case of sponsored research, result in a decision by the Vice President for Research to suspend the research project or refuse to approve a new sponsored research project for the individual who fails to comply.

A failure to comply also is subject to the full range of University disciplinary procedures, including:

- a. Formal admonition.
- b. A letter in the individual's file indicating that the individual's good standing as a member of the University has been called into question.
- c. Ineligibility of the individual to apply for grants, IRB approval, or supervision of graduate or professional students or trainees.
- d. Non-renewal of appointment.
- e. Termination of employment.

The person responsible for ensuring that an individual has complied with the University's Conflict of Interest and institutional conflict of interest policies must report a failure to comply to the Conflict of Interest Office, which refers it to the Conflict of Interest Committee, except that a failure to comply by the President or a member of the Board of Trustees must be reported to the Audit Committee of the Board of Trustees.

The Conflict of Interest Committee determines if the matter can be handled by requiring the individual to comply with a corrective action plan devised by the Conflict of Interest Committee. If so, the Conflict of Interest Committee devises the plan and advises the individual of its requirements. If the Conflict of Interest Committee determines that the matter cannot be handled by requiring the individual to comply with a corrective action plan, or the individual refuses to comply, the Conflict of Interest Committee refers the matter, along with its recommendations about how the matter should be handled, to the appropriate individual or body. In the case of faculty, the Conflict of Interest Committee refers the matter to the Provost. In the case of the Provost, General Counsel, Senior Vice President for Administration, Chief Financial Officer, Vice President for Medical Affairs, the Chief of Staff, the vice presidents for Development, University Relations, and Diversity, and any other individual that the President designates as a senior "cabinet-level" official, the Conflict of Interest Committee refers the matter to the President.

If an individual other than a non-faculty employee is dissatisfied with a determination of the Conflict of Interest Committee to impose a corrective action plan or with administrative action by the Vice President for Research to suspend or refuse to approve a sponsored research project, the individual may submit a written appeal to the Provost within 10 days of receipt of the determination. A non-faculty employee who is dissatisfied with a determination of the Conflict of Interest Committee may submit a written appeal to the Senior Vice President for Administration within 10 days of receipt of the decision.

If the Provost upholds the Conflict of Interest Committee's determination, the Provost's decision is final. If the Provost modifies or overrules the Conflict of Interest Committee's determination, the Conflict of Interest Committee may appeal to the President.

If the Senior Vice President for Administration upholds the Conflict of Interest Committee's determination, the decision of the Senior Vice President for Administration is final. If the Senior Vice President for Administration modifies or overrules the Conflict of Interest Committee's determination, the Conflict of Interest Committee may appeal to the President.

Grievance proceedings are conducted in accordance with the procedures provided in Chapter 3(I)(D) of the University Faculty Handbook and Section V-4 of the Human Resources Policy Manual.

V. Revisions to the Policies

Any revisions to these policies that are required by law or by government agency action automatically become part of these policies. Other revisions to these policies become effective upon being approved by the President, the Provost, and the Executive Committee of the Faculty Senate.

Glossary

“Faculty” – “Faculty,” as defined in the Faculty Handbook, comprises tenured or tenure track faculty members, non-tenure track faculty members, and special faculty members. Special faculty members are: 1) those persons holding part-time academic appointments, and 2) persons holding full-time academic appointments, but who have specific, limited responsibilities for the duration of a specific project, or for a limited duration. Examples of special appointments are faculty members hired for one semester, who teach one course on a repeated basis, who engage in clinical supervision only without other responsibilities to the University, or who are engaged in a specific project conducted outside the University.

“Financial interest” -- A “financial interest” includes income; honoraria; consulting fees; advisory board fees; membership on a speaker’s bureau; remuneration; gifts or other emoluments; “in kind” compensation; travel expenses, other than those paid for by the University or its hospital affiliates, or reasonable travel expenses paid for participation in scholarly and academic endeavors; equity such as stock, stock options or other ownership interests, including equity that individuals covered by this policy know they will inherit; royalties; non-university grants; debts; loans; non-university contracts; licensing agreements; inventors’ shares; and a board or other position in the private sector (including nongovernmental organizations (NGOs)) with advisory or fiduciary duties, even if uncompensated.

“Individual conflict of interest” – An outside interest that might adversely affect or appear to a reasonable person to adversely affect an individual’s judgment in carrying out University responsibilities, or that might adversely affect or appear to a reasonable person to adversely affect the University’s responsibility to the public, the safety of research subjects, or the integrity of research.

“Institutional conflict of interest” -- An institutional conflict of interest arises when the financial interests of the University, or a University official acting within his or her authority on behalf of the University, may influence or appear to influence the research, education, clinical care, business transactions, or other activities of the University; when an individual covered by this policy receives a financial or other benefit from the use or disclosure of non-public information pertaining to the University; and when outside activities are inconsistent with an individual’s responsibilities to the University.

“Investigator” – “Investigator” means the principal investigator and any other person who is significantly involved in the design, conduct or reporting of research, including the person’s spouse and dependent children. The term also includes investigators working for subgrantees, contractors, subcontractors, and collaborators.

“Outside activities” -- Outside activities include leadership participation in professional, community, or charitable activities, self-employment, participation in business partnerships, employment or consulting arrangements with entities other than the University, either compensated or uncompensated, and service on any board, including for-profit, non-profit, advisory, or honorary.

“Senior officials” – “Cabinet-level” officials of the University (comprising the President, Provost, General Counsel, Senior Vice President for Administration, Chief Financial Officer, Vice President for

Medical Affairs, the Chief of Staff, the vice presidents for Development, University Relations, and Diversity, and any other individual that the President designates).

**Adopted by the Board of Trustees 10/11/77; amended 5/11/79 and 5/13/81; amended and approved by the Faculty Senate 1/27/09 and the Board of Trustees 2/20/09; red text approved by Faculty Senate 4/21/11; pending BOT approval.*

IX. Copyright Compliance Policy*

As one of the nation's major research institutions, Case Western Reserve University is committed to leadership in the creation of new knowledge, and also is committed to respect for the rights of all copyright holders. In the discovery, use, and dissemination of knowledge, the University fosters integrity in the pursuit of scholarly investigation while contributing to society as a whole.

Respect for the rights of copyright holders and the copyright laws is especially critical in the electronic environment, where copyrighted works are vulnerable to misuse and unintended further distribution, and legislation is evolving with significant new fines and liabilities for non-compliance. The University's Copyright Compliance Policy supports academic goals and values in a time of changing laws and information technologies and complements the University Intellectual Property Policy and the Acceptable Use of Computing and Information Technology Resources Policy. It is predicated on the belief that accurate information about copyright encourages the proper use of copyrighted materials, eliminates common misconceptions, and reduces the peril of individual and institutional risk. In an effort to create an environment in which all members of the University community lawfully use copyrighted materials, the Policy:

- outlines foundations of copyright that are relevant to the academic mission
- promotes respect for copyright holders' rights
- defines criteria and requirements for compliance with federal copyright laws
- informs University individuals about beneficial and legal exemptions
- offers avenues for continuing information and education about copyright laws.

This document describes the legal requirements and benefits of copyright compliance in order to be helpful to faculty, staff, and students of the University. As such, it offers information and clarification about compliance with relevant portions of the United States Copyright Act. Additional resources, including the full text of laws referred to in this Policy, are in Appendix E.

1. Policy Statement

The University expects all faculty, students, and staff to abide by the Copyright Compliance Policy and to be familiar with federal copyright laws relevant to the academic use of copyrighted materials.

The University's reputation as a leader in research and information technologies is strengthened and protected by copyright compliance.

All members of the University community need to understand that copyright infringement may have serious consequences, including significant personal liability for them. The University assumes no liability for, and is not obligated to defend, individuals who knowingly fail to comply with the