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CASE WESTERN RESERVE UNIVERSITY

2022 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 University research, post-doctoral fellows and scholars, non-faculty employees, students, and trainees. The specific policies cover specific types of individuals.

For research and investigators funded by the Public Health Service of the U.S. Department of Health and Human Services (PHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH), there are specific definitions and processes that CWRU will apply.

Availability of the Policy

The University will maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with applicable regulations, including any federal financial conflict of interest regulations. The policy will be posted and available via a publicly accessible web site. The University will inform covered individuals of the policy and of their responsibilities regarding disclosure. The University will inform covered individuals in the event that the policy is revised and updated.

The University Conflict of Interests Committee

The members of the Conflict of Interests Committee, including the leadership of the committee, are appointed by the President and include faculty, non-faculty employees, and administrators. The Conflict of Interests Committee includes at least one member of the public who serves as a regular member of the Conflict of Interests Committee, and a second member of the public who serves as an alternate member of the Conflict of Interests 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 Interests 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.

The Conflict of Interests Committee is supported by the Conflict of Interests Committee Staff.

Members of the Conflict of Interests 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 special faculty members, unless engaged in University research; emeritus faculty members who have an ongoing relationship with the University, e.g., who are applying for or engaged in University research; post-doctoral fellows; all employees; students; and trainees. “University faculty” members are those individuals defined as such 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. Disclosure

“Disclosure” means an individual’s disclosure of financial interests and/or significant financial interests to the University.

The disclosure 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 disclosure requirement does not indicate that the activity in question is in any way objectionable; indeed, disclosure is required in connection with many activities in which members of

the University are expected to engage, such as funded research, or that are otherwise praiseworthy, such as the receipt of honorary awards.

1. Who must disclose?

The following individuals must disclose 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 special faculty members, unless engaged in University research; emeritus faculty members who have an ongoing relationship with the University, e.g., who are applying for or engaged in University research; 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. Individuals who have no disclosable interests must still submit an annual disclosure form to be in compliance with this policy.

Students and post-doctoral fellows and scholars do not have to disclose unless they contribute to the scientific development or execution of a research project in a substantive way.

For PHS and NIH-funded research there are specific designations for research personnel. “Investigator” means the Project Director, Principal Investigator and any other person who is significantly involved in and responsible for the design, conduct or reporting of research, or proposal for such funding. The term also includes investigators working for subgrantees, contractors, subcontractors, and collaborators. See also the definitions provided in this policy for “Project Director/Principal Investigator” and “Senior/key personnel.”

2. What activities must be disclosed?

Individuals covered by this policy must disclose any financial interest (defined in the attached Definitions) 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. “Institutional responsibilities” are defined as those professional responsibilities that are conducted on behalf of the University. Examples of institutional responsibilities 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. Management of Institutional Conflicts of Interest is detailed in Part II of this policy (“Institutional Conflict of Interest”) and the Definitions section of this policy.

Individuals covered by this policy who engage in research must disclose 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 disclose 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 disclose whenever a previously disclosed conflict of interest is eliminated.

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

3. What activities are permitted without disclosure?

Certain activities may be engaged in without disclosure. Typically, these are activities not covered in section 2 above, and in which academics routinely engage and in which an individual’s financial interests are not expected to influence his/her judgment. Disclosure is also not required for salary, royalties or other remuneration paid by the University to the individual if the individual is currently employed or otherwise appointed by the University.

Examples of activities in which individuals may engage without disclosure 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.

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

Travel that is reimbursed or sponsored by a federal, state or local government agency, an institution of higher education within the United States as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. This exclusion is limited to entities located within the United States, and therefore, when these interests are associated with the governments of another country, which includes local, provincial, or equivalent governments of another country (i.e., not within the United States) or foreign institutions of higher education, they must be disclosed.

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 within the United States as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. This exclusion is limited to entities located within the United States, and therefore, when these interests are associated with the governments of another country, which includes local, provincial, or equivalent governments of another country (i.e., not within the United States) or foreign institutions of higher education, they must be disclosed.

Income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education within the United States as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. This exclusion is limited to entities located within the United States, and therefore, when these interests are associated with the governments of another country, which includes local, provincial, or equivalent governments of another country (i.e., not within the United States) or foreign institutions of higher education, they must be disclosed.

Royalties or other payments extending from intellectual property rights assigned to the University, and agreements to share in royalties or other payments related to such rights.

Grants and contracts administered through the University.

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

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

All members of the University community are covered by the Conflict of Interest policy, but disclosure requirements vary according to the individual's role(s) with the University.

Generally, annual disclosure is made to the Conflict of Interests Committee using the form provided by the University.

Members of the Board of Trustees, the President, and other senior officials disclose using a separate process administered by the Office of the General Counsel.

Those staff members and other individuals who are not required to complete an annual disclosure form must disclose to their supervisors any financial interest that relates to their University responsibilities. Supervisors who determine that an individual may have a conflict of interest must report this to the Conflict of Interests Committee for further review.

Compliance with this policy does not relieve the individual from complying with pertinent regulatory committee disclosure requirements.

5. When is disclosure to be made?

Disclosure must occur at least annually in accordance with the time period prescribed by the University. For those who are listed on sponsored projects, disclosure must occur no later than the time of funding application. Individuals also must disclose, as appropriate, within 30 days of discovering or acquiring a disclosable interest or within 30 days after a financial interest has been eliminated.

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

Disclosure or confirmation/updating of previously disclosed information 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 as required.

D. Review

1. What is the process?

The Conflict of Interests Committee Chair and Staff, or the Office of General Counsel Staff, as appropriate, conducts an initial review of all the disclosures they receive.

If necessary, they obtain additional information from the disclosing individual and from other individuals who possess relevant information. The Conflict of Interests Committee Chair and Staff, or the Office of the General Counsel Staff, as appropriate, notifies the Conflict of Interests Committee or the Board of Trustees, respectively, of those activities that must be further reviewed. Reviews of individual disclosures conducted solely by the Audit Committee of the Board of Trustees are conducted according to the rules of the Board of Trustees.

The Conflict of Interests Committee reviews all disclosures to determine whether the disclosed financial interests represent a significant financial interest (SFI), whether they are related to the individual's University responsibilities, including research, and whether a management plan is required. For all research projects, including PHS funded research, the review for relatedness of significant financial interests includes an assessment of whether these interests are financial conflicts of interest (FCOI) that could directly and significantly affect the design, conduct, or reporting of the research. An SFI is an FCOI when the SFI is determined by CWRU's designated official(s) to be "related to the research" (i.e., the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research.)

In conducting review, the Conflict of Interests Committee considers a number of factors, including the value of the individual's financial interest; and in the case of research, whether the individual is uniquely qualified by virtue of expertise and experience to conduct the research project, whether 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. While serving as an investigator on a research project that relates to a company's products, an individual is receiving consulting fees from and/or has equity in the company.
- b. An individual manages the renovation of departmental offices and participates in the selection of an architectural firm in which his spouse is a partner.
- c. While serving on the board of directors of a business, an individual acts as an investigator on research sponsored by the business.
- d. An individual makes referrals to a business in which he or she has a financial interest.

2. Management

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

To "manage" means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflicts of interest, and, in the case of conflicts of interest involving research, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

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 relevant review bodies, as required; 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 Interests Committee.

Management plans are developed according to the nature of the significant financial interest and of the related University activity, e.g., whether there is an institutional as well as an individual conflict of interest, and whether the investigator is conducting research.

The Conflict of Interests Committee may involve the individual in the conflict of interest assessment. If the Conflict of Interests Committee determines a management plan is required, then upon finalizing the management plan, the Conflict of Interests Committee will provide the management plan to the individual and inform the individual that the management plan is in effect.

E. Training

Information regarding the University's conflict of interest policy and procedures will be made available to the University community. All individuals required to disclose will receive pertinent information regarding disclosure requirements. The University will comply with federal financial conflict of interest regulations regarding providing training on requirements, including disclosure requirements for investigators applying for and engaged in PHS-funded research.

F. Reporting

The University will comply with federal regulations regarding reporting of financial conflicts of interest, e.g., by submitting financial conflict of interest reports to the awarding component, as required.

The University will comply with federal financial conflict of interest regulations regarding making publicly available information on identified financial conflicts of interest held by investigators and key personnel on PHS-University research.

CWRU will respond meaningfully to any requestor within five business days of information concerning any significant financial interest related to PHS funding. The response will include the following criteria:

- a. The significant financial interest was disclosed and is still held by the investigator or senior/key personnel;
- b. CWRU determines that the significant financial interest is related to the PHS-funded research; and
- c. CWRU determines that the significant financial interest is a financial conflict of interest.

G. Subrecipient Reporting

The University will comply with federal conflict of interest regulations regarding subrecipient agreements, including for PHS-funded awards.

H. Record Keeping

The University complies with federal regulations regarding maintaining records relating to all disclosures of financial interests and the University's review of, and response to, such disclosures.

I. Appeals

If an individual covered by this policy who is a faculty member is dissatisfied with a determination of the Conflict of Interests Committee, the individual may submit a written appeal to the Provost within 10 days of receipt of the decision. The appeal shall be decided by the Provost or his/her designee. The Provost or

his/her designee will make best efforts to render a decision in writing within 30 days of receipt of the appeal. If the Provost upholds the Conflict of Interests Committee's determination, the Provost's decision is final. If the Provost modifies or overrules the Conflict of Interests Committee's determination, the Conflict of Interests Committee may appeal to the President.

A non-faculty employee who is dissatisfied with a determination of the Conflict of Interests Committee may submit a written appeal to the Senior Vice President for Administration within 10 days of receipt of the decision. The appeal shall be decided by the Senior Vice President or his/her designee. The Senior Vice President or his/her designee will make best efforts to render a decision in writing within 30 days of receipt of the appeal. If the Senior Vice President for Administration upholds the Conflict of Interests 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 Interests Committee's determination, the Conflict of Interests Committee may appeal to the President.

If the individual is the President or senior official, the President or senior official 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.

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 Interests 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 of a University official acting within his/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/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. Disclosure

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

In addition, the Conflict of Interests Committee Staff 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 Interests 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 Office of Research and Technology Management, a list of the University's equity holdings and technology licenses.

D. Review

1. What is the process?

Reviews of individual disclosures 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 individual disclosures, the Conflict of Interests Committee Chair and Staff, or the Office of General Counsel Staff, as appropriate, conducts an initial review. If necessary, they obtain additional information from the disclosing individual and from other individuals who possess relevant information.

The Conflict of Interests Committee Chair and Staff utilize information provided by the offices and departments of the institution (e.g., 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) to review potential institutional conflicts of interest received.

The Conflict of Interest Chair and Staff then identify those activities that must be further reviewed by the Conflict of Interests Committee. The Conflict of Interests Committee will review the disclosures it receives to determine whether the disclosed financial interests of institutional officials or of the University are significant and whether they are related to University activities, and, if so, whether management is required to manage the institutional conflict of interest.

In conducting review, the Conflict of Interests Committee considers a number of factors, including value of the institutional financial interest and the nature of related University activities.

The review for both individual and institutional significant financial interests include a review of relatedness for both institutional responsibility and research. Specifically, in the case of NIH-funded research, the review for relatedness of significant financial interests includes an assessment of whether these interests are financial conflicts of interest (FCOI) that could directly and significantly affect the design, conduct, or reporting of the research.

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. A vice president of the University signs off on a procurement decision involving major purchases from or supply contracts with a commercial entity of which he is a director.
- b. A department chairman serves as an investigator in a research project sponsored by a company from which she receives consulting income.
- c. As patent-holder, the University stands to gain royalties from intellectual property licensed to a company, and that intellectual property is being investigated under a research contract with the University.
- d. A company that has made a major gift to the University has requested special consideration in the bidding process as a vendor. The individual considering the bid is a consultant for the company.
- e. A start-up company partially owned by the University has requested a discounted rate in utilizing several University core facilities. The facilities are overseen by an individual who is the chief scientific officer of the company.

2. Management

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

- a. Isolating the individual from involvement in research or decision-making regarding research.
- b. 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.
- c. 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.
- d. Requiring the individual to recuse him- or herself from institutional decisions regarding the outside entity that is source of conflict.
- e. 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 Research Administration, 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.
- f. 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.
- g. Prohibiting the research from taking place at the University.
- h. Eliminating, reducing, or modifying the University's financial stake in an outside entity or research project.
- i. Enhancing or creating firewalls or other conflict-management systems to separate financial and research decision-making.

- j. 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).
- k. Preventing the individual from serving as the principal investigator, co-principal investigator, or investigator on the research project.
- l. 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.
- m. Prohibiting the individual from participating in institutional negotiations with the outside entity except as the University directs.
- n. 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.
- o. Prohibiting the individual from disclosing confidential University information.
- p. Prohibiting the individual from channeling discoveries to the outside entity.
- q. Prohibiting the University from accepting research grants from companies founded by the individual.

E. Appeals

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

In the event that an individual who is charged with executing an institutional conflict of interest management plan but who does not have an individual conflict of interest is dissatisfied with a determination of the Conflict of Interests 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 Interests Committee's determination, the decision is final. If the President modifies or overrules the Conflict of Interests Committee's determination, the Conflict of Interests Committee may appeal to the Audit Committee.

III. Confidentiality

All information contained in disclosures or obtained in the course of reviewing a potential conflict of interest or institutional conflict of interest, is kept confidential, subject to the University's reporting obligations to government agencies, research sponsors and the public. The information is available to the Conflict of Interests Committee and its Staff, and to the individuals charged with the responsibility for review in the particular case. In addition, the disclosures received by the Conflict of Interests Committee are shared with the deans and department chairs or supervisors of the disclosing individuals at the request of the individual's dean, chair or supervisor, or at the request of the Conflict of Interests Committee. The individual's department chair, dean or supervisor will be provided with the management plan. There may be

instances when other institutional officials must receive this information (e.g., members or staff of regulatory committees with oversight of activities covered in the management plan).

IV. Sanctions

Failure to comply with these policies includes failing to submit a required disclosure, 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 University research, result in a decision by the Vice President for Research to suspend the research project or refuse to approve a new University 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. Additional sanctions per research funding agency may apply (such as requiring investigator financial conflict of interest training), up to and including sponsor suspension of funding per applicable federal regulations. The University will comply with federal financial conflict of interest requirements regarding non-compliance retrospective review and corrective action.
- e. Non-renewal of appointment.
- f. Termination of employment.

The person responsible for ensuring that an individual has complied with the University's Conflict of Interest Policy must report a failure to comply to the Conflict of Interests Committee Chair or Staff, who refers it to the Conflict of Interests 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 Interests Committee determines if the matter can be handled by requiring the individual to comply with a corrective action plan devised by the Conflict of Interests Committee. If so, the Conflict of Interests Committee devises the plan and advises the individual of its requirements. If the Conflict of Interests 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 Interests 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 Interests 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 Interests 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 Interests Committee to impose a corrective action plan or with administrative action by the Vice President for Research to suspend or refuse to approve a University 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 Interests 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 Interests Committee's determination, the Provost's decision is final. If the Provost modifies or overrules the Conflict of Interests Committee's determination, the Conflict of Interests Committee may appeal to the President.

If the Senior Vice President for Administration upholds the Conflict of Interests 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 Interests Committee's determination, the Conflict of Interests Committee may appeal to the President.

Grievance proceedings are conducted in accordance with the procedures provided in the University Faculty Handbook and 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 will 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.

Definitions

"Disclosure" – "Disclosure" means an individual's disclosure of financial interests and/or significant financial interests to the University.

"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 conflict of interest report" - In the sponsored research context, this refers to the University's financial conflict of interest report to the awarding component.

"Financial interest" – A "financial interest" means anything of potential monetary value, whether or not the value is readily ascertainable. Examples of financial interests include the following: income; honoraria; consulting fees; advisory board fees; membership on a speaker's bureau; remuneration; gifts or other emoluments; "in kind" compensation; travel expenses and reimbursement, other than those paid for by the University or its hospital affiliates, or reasonable travel expenses paid for participation in scholarly and academic endeavors and/or those described in the exclusions in Section I.C.3. of this policy; 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. Disclosure of a board membership or other officer position involving advisory or fiduciary duties with any outside entity is required where: 1) the individual receives compensation from the entity (i.e., salary or other remuneration; equity interest, such as stock, stock options or other ownership interest; or other compensation of monetary value); or 2) the board or officer position (whether compensated or uncompensated) is with a for-profit outside entity or with an outside entity (for-profit or non-profit) that has a vendor or sponsor relationship with the University or its clinical affiliates, to the best of the individual's knowledge.

"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. For the purposes of research, a financial conflict interest means a significant financial interest that could directly and significantly affect the

individual's University responsibilities, and in the case of research, that could directly and significantly affect the design, conduct, or reporting 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/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.

“Institutional responsibilities” – “Institutional responsibilities” are defined as those professional responsibilities that are conducted on behalf of the University. Examples of institutional responsibilities 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.

“Investigator” – “Investigator” means the Project Director, Principal Investigator and any other person who is significantly involved in and responsible for the design, conduct or reporting of research, or proposal for such funding. “Individual” includes the person's spouse and dependent children and/or any other collaborators or consultants. The term also includes investigators working for subgrantees, contractors, subcontractors, and collaborators. See also the definitions provided in this policy for “Project Director/Principal Investigator” and “Senior/key personnel.”

“Manage” – “Manage” means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflicts of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

“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.

“PHS” –Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

“Project Director/Principal Investigator”– These terms refer to the project director or principal investigator of a research project. See also the definitions provided in this policy for “Investigator” and “Senior/key personnel.”

“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).

“Senior/key personnel” – These terms are used interchangeably to refer to the Project Director/Principal Investigator and any other senior or key personnel identified by the University on PHS-funded grant applications, progress reports, or any other reports to the PHS by the University. See also the definitions provided in this policy for “Investigator” and “Project Director/Principal Investigator.”

“Travel expense disclosure” - Disclosure of travel expenses and reimbursement is required for travel that is not reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education within the United States 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. When these interests are associated with the governments of another country, which includes local, provincial, or

equivalent governments of another country (i.e., not within the United States) or foreign institutions of higher education, they must be disclosed.

Disclosure of the nature of the travel will be accomplished on the annual disclosure form.

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