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CASE WESTERN RESERVE UNIVERSITY

2023 POLICIES ON INDIVIDUAL FINANCIAL CONFLICTS OF INTEREST AND INSTITUTIONAL CONFLICTS OF INTEREST

Introduction

This document establishes policies on individual financial 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.

With regard to research funded by, including plans to participate in research 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 the University will apply to promote compliance with the federal regulation 42 CFR Part 50 Subpart F, "Promoting Objectivity in Research," applicable to PHS grants and cooperative agreements.

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 FCOI regulation, this policy and of their responsibilities regarding disclosure of financial interests. 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 Financial Conflict of Interest Policy

A. Who is covered by this policy?

The **financial** 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.

With regard to PHS/NIH-funded research, a Financial Conflict of Interest occurs when an individual has a Significant Financial Interest that is related to the PHS/NIH-funded research (i.e., the SFI could be affected by the research or the SFI is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct or reporting of PHS-funded research.

C. Disclosure

"Disclosure" means an individual's disclosure of 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.

2. What activities or financial interests 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 and financial interests 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 located in the United States, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States 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 individual 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 located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States 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 located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States 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. Typically, annual disclosure is completed between February and April each year. 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 outside interests sufficiently in advance of their start date that the interests can be reviewed and any conflicts 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) (see Definitions), 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 related to the research (i.e., the SFI could be affected by the research or the SFI is in an entity whose financial interests could be affected by the research) and whether they represent financial conflicts of interest (FCOI). An FCOI means an SFI could directly and significantly affect the design, conduct, or reporting of the research.

An SFI is an FCOI when the SFI is determined by the University's designated official(s) to be "related to the Public Health Service (PHS) (e.g., National Institutes of Health [NIH])- funded research" (i.e., the SFI

could be affected by the PHS/NIH-funded research or is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct or reporting of the PHS/NIH-funded research. "Significantly" means the financial interest would have a "material effect" on the research (page 53621 of the Preamble to the Final Rule).

In conducting a 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, professional audiences with whom the research or other activity is discussed orally or in writing, and human subject research participants in the informed consent document.)

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 individual 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 complete training prior to engaging in NIH-funded research and annually when they complete their disclosure form. The University will comply with federal financial conflict of interest regulations by providing training on the FCOI regulation, the University's policy requirements, and individual disclosure requirements, including disclosure requirements for Investigators applying for and engaged in PHS-funded research.

In addition, training will occur immediately under the following circumstances: (1) Institutional Financial Conflict of Interest policies change in a manner that affects Investigator requirements; (2) An Investigator is new to the Institution; and (3) The Institution finds that an Investigator is not in compliance with the Institution's Financial Conflict of Interest policy or management plan.

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 NIH awarding component via the eRA Commons FCOI Module, as required. Reports will include, at a minimum, the project number, PD/PI or Contact PD/PI if a multiple PD/PI model is used, the name of the Investigator with the FCOI, the name of the entity with which the investigator has a FCOI, the nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium), the value of the financial interest or a statement that the interest is one whose value cannot be readily determined, a description of how the financial interest relates to the NIH-funded research and why the institution determined that the financial interest conflicts with such research, and a description of the key elements of the institution's management plan.

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

The University 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 senior/key personnel;

b. The University determines that the significant financial interest is related to the PHS-funded research; and

c. The University 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. The University is responsible for ensuring any subrecipient's compliance with the regulation and reporting identified financial conflicts of interests for subrecipient Investigators to the NIH. The University will incorporate as part of a written agreement with a subrecipient terms that establish whether the University Financial Conflict of Interest policy or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or Financial Conflict of Interest reporting requirements.

Subrecipient Institutions who rely on the University's Financial Conflict of Interest policy will report identified financial conflicts of interests to the University in sufficient time to allow the University to report the Financial Conflict of Interest to the NIH to meet its reporting obligations.

Subrecipient institutions that must comply with the University's policy must submit all Investigator disclosures of Significant Financial Interests to the University in sufficient time to allow the University to review, manage and report identified FCOIs to the NIH. The University will monitor the subrecipient's compliance with the Financial Conflict of Interest regulation, management plans, and reporting all identified financial conflicts of interest to the NIH.

H.Mitigation

Retrospective Review
Mitigation plan and review will comply with federal regulations 42 CFR 50.604(b) regarding providing training on federal requirements for investigators applying for and engaged in PHS-funded research. Whenever a financial conflict of interest is not identified or managed in a timely manner, including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the Institution shall, within 60 days of identifying an FCOI, review the significant financial interest, determine whether it is related to PHS-funded research, and determine whether a financial conflict of interest exists, and if so implement on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward.

In addition, within 120 days of the Institution's determination of noncompliance, the institution will complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. The mitigation report will include project number, project title, PD/PI or contact PD/PI if a multiple PD/PI model is used; name of the

investigator with the financial conflict of interest; name of the entity with which the Investigator has a financial conflict of interest; reason for the retrospective review, detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed), findings of the review, and conclusions of the review.

Based on the results of the retrospective review, if appropriate, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Institution will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

Thereafter, the Institution will submit FCOI reports annually. Depending on the nature of the financial conflict of interest, the Institution may determine that additional interim measures are necessary regarding the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution retrospective review. Whenever the Institution implements a management plan, the Institution will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

Additional Mitigation for Clinical Research
In any case in which U.S. Department of Health and Human Services (HHS) determines that a PHS-funded project included clinical research, with the purpose to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution as required by 42 CFR 50.606 (c), the Institution will require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

I. 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. The University will keep all records of all Investigator disclosures of financial interests and the Institution's review of, or response to, such disclosure (whether or not a disclosure resulted in the Institution's determination of a Financial Conflict of Interest), and all actions under the Institution's policy or retrospective review, if applicable. Records of financial disclosures and any resulting action will be maintained by the Institution for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 75.361. The University will retain records for each competitive segment.

J. 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 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 monetary value, whether or not the value is readily ascertainable.

"Individual" – The term "Individual", when used in this policy, includes the "Investigator" (as defined below), and the investigator's spouse and dependent children.

"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. With regard to PHS and NIH-funded research, a Financial Conflict of Interest occurs when an investigator has a Significant Financial Interest that is related to the PHS/NIH-funded research (i.e., the SFI could be affected by the research or the SFI is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct or reporting of PHS-funded 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 or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants. For the purposes of disclosure, an "Investigator" must disclose as an "Individual", including relationships of their spouse and dependent children.

"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" – The Project Director/Principal Investigator and any other person identified by the University on PHS-funded grant applications, progress reports, or any other reports to the PHS by the University. This definition is included as it relates only to the public accessibility requirement. The University is required to make certain FCOI information publicly available for those individuals who are identified as senior/key personnel.

"Significant financial interest" – "Significant financial interest" is
(1) A financial interest consisting of one or more of the following interests of the individual (including those of the individual's spouse and dependent children) that reasonably appears to be related to the individual's institutional responsibilities: (i) With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value; (ii) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.,* that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency located in the United States, a United States Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a Untied States

Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

"Foreign Reimbursed or Sponsored 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 located in the United States, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education. Individuals are required to disclose all reimbursed or sponsored travel received from a foreign government, which includes local, provincial, or equivalent governments of another country (i.e., not within the United States) or a foreign institution of higher education. Disclosure of the nature of the travel will be accomplished on the annual disclosure form.

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