

Title: CONFLICT OF INTEREST POLICY

Responsible Official: Executive Vice President for Research and Economic Development

Responsible University Office: Office of Research and Technology Management

Revision History: Adopted by the Board of Trustees 10/11/77; amended 5/11/79 and 5/13/81; amended and approved by the Faculty Senate 1/27/09 and the Board of Trustees 2/20/09; revised with the approval of the President on 6/19/09; amended by the Faculty Senate Executive Committee on 4/11/12 and endorsed by the Faculty Senate 4/25/12 as well as the Board of Trustees on 6/2/12. The Faculty Senate Executive Committee further amended the policy on 12/06/12. The Office of Research Administration amended the policy on 4/3/23 and 5/4/2026 with the approval of the President on 6/12/2026.

Related legislation and University policies: 42 CFR Part 50, Subpart F; 2 CFR 200; Procurement Policy

Review Period: As needed per federal regulations but at least every five years

Date of Last Review: May 4, 2026, with amendments.

Relates to: Faculty, Staff, Students, Post docs, Trustees

See also: Additional Guidance and Frequently Asked Questions

I. GUIDING PRINCIPLES AND POLICY SUMMARY

A. General Principles

To maintain public trust in Case Western Reserve University, (CWRU, university, University) all members of the university community, including our leadership, faculty, staff, postdoctoral scholars, and graduate and undergraduate students, must conduct the affairs of the university with transparency, integrity, objectivity, and good judgement using the highest ethical and legal standards. Key to being a respected and vital partner in our university community is the ability to trust the judgement and actions of our university members in business, academic, and research endeavors. Transparency in properly disclosing individual outside interests and personal activities is paramount.

Any ambiguity or failure to disclose reportable information will erode trust in the university in all our engagements with each other, investors, funders, and the larger community and is therefore considered unacceptable. University decisions, actions, and research must be conducted with objectivity and be free from bias related to individual outside interests and activities. Finally, all members of the university community must use good judgment when acting on behalf of the university.

B. Definition of Conflict of Interest

Conflicts of interest may be activities or engagements that appear to or actually influence or distort the way an individual makes decisions or performs university responsibilities. A conflict is identified when personal interests, outside employment, service, or other outside activities of a member of the university community or their immediate family members (spouse, domestic partner or dependent children living in the same household) could directly or significantly affect the performance of institutional responsibilities, including research. Conflicts of interest are not inherently negative but instead are considered to be a routine aspect of university life. Most can be acceptably managed by university processes.

Conflicts can be direct, immediate, and result in financial gain or lead to other personal or professional gains that go beyond financial reward. Conflicts of interest can be actual, potential, or perceived. Conflicts of interest can also be significant or insignificant. The appearance of distortion in decision making related to conflicts of interest is managed routinely through transparency and disclosure.

C. Policy Summary

This document establishes the policy on individual conflicts of interest (COI) and outside interest reporting. All members of the university community are expected to abide by the principles outlined within this policy. Members of the university community are encouraged to engage in relationships with business entities to further the university's mission while acknowledging that inherent in these relationships is the risk that professional judgment may be improperly influenced by the existence of such relationships.

This policy does not aim to eliminate valuable collaborations that may have inherent conflicts. Instead, it provides guiding principles and procedures to manage these conflicts, ensuring that research integrity and public trust in the university can endure alongside partnerships. The policy outlines necessary disclosure steps, oversight processes, and transparency standards that enable identifying and mitigating risks of bias proactively.

D. Disclosure of Outside Interests

Individuals Required to Disclose are defined as full-time, Board-appointed university faculty members; executive and senior level staff members (salary grade is 18 or above or equivalent); those with purchasing or signatory authority; those responsible for the design, conduct and reporting of research; and anyone asked to disclose by the Research COI Committee or Compliance Office. Those who are identified as Individuals Required to Disclose must disclose their outside interests using the identified disclosure system.

All Individuals Required to Disclose are required to abide by this policy, by fully disclosing professional and relevant personal activities and relationships that create or have the appearance of a conflict of interest as required by the university. Individuals Required to Disclose are to remain aware of the potential for conflicts of interest; take initiative to manage, disclose, or resolve conflicts of interest as appropriate; and are expected to comply with any management or monitoring plan prescribed by the university.

The university maintains and enforces this written policy on financial conflicts of interest (FCOI) that complies with applicable regulations including federal financial conflict of interest regulations. The policy is posted and available publicly. The university informs Individuals Required to Disclose of the FCOI regulation, this policy, and of their responsibilities regarding disclosure of financial interests. The university informs Individuals Required to Disclose if the policy is revised or updated. Any revisions to this policy that are required by law or by government agency action will become part of this policy.

Additional requirements also apply to Individuals Required to Disclose who participate in, or plan to participate in, research funded by federal agencies such as the Public Health Service (PHS) of the US Department of Health and Human Services (including the National Institutes of Health (NIH)). These additional requirements are included in the COI Policy, Appendix A.

E. Board of Trustees

The disclosure and management process concerning actual or potential conflicts of interest involving any of the Trustees is the responsibility of the Board of Trustees as provided for in the university Bylaws.

II. FINANCIAL COI PRINCIPLES

Conflicts of interest can arise from various circumstances. These COI principles set forth standards to follow for both the university community and Individuals Required to Disclose. No policy, set of principles, guidelines, nor list of rules can provide direction for all circumstances that could arise. All members of the university community will use good judgment when acting on behalf of the university.

A. Relationships with Outside Businesses

Members of the university community with administrative responsibilities or who can direct the use of university assets must take particular care to avoid relationships and activities in which financial interests or other personal interests overlap with the university's interest and have the potential for the individual to consider inappropriate factors while making administrative decisions about university business.

Members of the university community may not review, evaluate, approve, negotiate, or administratively control contracts or business relationships when the contract or business relationship is between the university and a business in which the individual has a financial interest.

B. Receiving Gifts

The university may accept gifts in furtherance of its missions. All gifts given to the university must be directed through the Division of University Relations and Development. Neither the university nor members of the university community may receive gifts that would place them in a prejudicial or compromising position, interfere in any way with the impartial discharge of their duties to the university, or reflect adversely on their own integrity or the integrity of the university.

In a university setting, professional life and professional relationships occasionally give rise to situations where a member of the university community may appropriately receive a gift from a current student, a person external to the university, such as a collaborator at another institution, or a business organization, such as a vendor. Members of the university community may accept nominal gifts of appreciation from current students, or their families, provided the gift is not considered extravagant.

Members of the university community may accept gifts, meals, entertainment, and other ordinary social amenities, whether the source is an individual or a business, provided that such amenities are not otherwise extravagant under the circumstances. In accepting a gift, individuals must keep themselves free from any obligation concerning referral of business to that person or business organization. Inexpensive novelty, advertising, or promotional items such as calendars, pens, mugs, caps, and t-shirts are not considered to be gifts.

Members of the university community may not accept anything at all, or gifts of any amount, from applicants to the university or their families.

C. Use of University Assets

The university holds both tangible and intangible assets. Assets include buildings, personnel, equipment, patents, copyrights, technology, work products, and licensed resources, funds, confidential information, and reputation. Members of the university community are expected to protect the best interests of the university in the use of all university resources and assets.

Use of the university's assets in connection with any individual or personal outside activity or interest is prohibited. This includes representing or implying that the university has endorsed an activity, such as by use of the university's logo or name.

D. Individuals who Provide Patient Care

Members of the university community who are involved with the administration of patient care may be subject to separate policies and procedures based on their additional affiliations, including within their schools, including CWRU Schools of Medicine and Dentistry, clinics, hospitals, and professional organizations.

E. Trainees

Members of the university community may not allow their outside interests to delay or impede the academic progress or goals of their trainees. Trainees are defined as those members of the university community who are advised, formally mentored, or supervised, and include individuals serving in the roles of faculty, research staff, postdoctoral scholars, clinical fellows, and graduate and undergraduate students.

As members of the university community, trainees must maintain awareness of their responsibility to discuss with their faculty supervisor any outside activities that are related to their scholarly work. Trainees may be required to disclose those interests.

F. Personal Engagement in Externally Sponsored Activities

Personal engagement in externally sponsored activities occurs when a sponsor provides support directly to a member of the university community that could appear to conflict with the individual's CWRU responsibilities. Personal engagement in externally sponsored activities occurs when the university is not involved in negotiating the activity, and any payment or benefit is provided directly to the member of the university community. Individuals required to disclose must disclose these activities, which may include sponsored or reimbursed travel, invited presentations or lectures (with or without compensation) consulting agreements directly negotiated with industry, and membership on boards of directors.

III. DUTY TO DISCLOSE OUTSIDE INTERESTS

This policy requires individuals required to disclose as identified in Section I.D., to periodically disclose their outside interests. The disclosure form and processes are designed to facilitate clear, complete, and detailed disclosure information that aligns and complies with this policy and its definitions (See Appendix B: Definitions).

For individuals required to disclose their outside interests, submission of a disclosure form is required even if there are no outside interests to disclose. Failure to disclose information in a complete and timely manner jeopardizes the university mission and our university community. In addition, failure to disclose potential conflicts may result in both individual consequences and institutional sanctions, including barriers or loss of eligibility to apply for research funding, acceptance of research funds, or approval of research awards or other projects.

The university strives to maintain the confidentiality of information contained in disclosures or obtained while reviewing potential conflicts of interest. Strict confidentiality will always be maintained unless subject to certain reporting obligations to government agencies, research sponsors, and the public.

Collection, review, and management of disclosures varies depending on an individual's primary role and responsibilities at the university.

A. Individuals Required to Disclose

Individuals required to disclose, as identified in Section I.D., must disclose their outside interests using the identified disclosure system.

Individuals required to disclose may have additional disclosure requirements beyond this policy to both internal university offices (e.g., Faculty Activity Reports) and external organizations, including funding agencies, sponsors, in publications and presentations, to other employers, and professional organizations. Individuals required to disclose must review and update their disclosures as necessary when university roles change, responsibilities change, when new research activities begin, and when there is a change in scope to current research activities.

Those not involved in research but considered individuals required to disclose must disclose their outside interests on an annual basis. The disclosure procedures of the university Office of Compliance apply to individuals who are required to disclose but are not involved in the design, conduct, or reporting of research. The Compliance Office reviews the outside entities that have been disclosed, together with other internal university offices, to monitor compliance with this policy.

B. Individuals Required to Disclose Involved in Research

Research, scholarship, and other creative endeavors have enormous potential to benefit humankind, and the university strongly supports efforts to bring discoveries to society. Conflicts of interest in research involve situations in which financial, professional, or other personal considerations may distort or have the appearance of distorting an individual's judgment in the design, conduct, or reporting of research. All individuals required to disclose who engage in research must disclose, using the university's disclosure

platform, any financial interests in any entity that sponsors or supports the research or holds a financial interest in the subject of the research.

Individuals involved in the design, conduct, or reporting of research must complete an initial disclosure form to be eligible to apply for external funding. When there are changes to their outside interests, the individual must update their disclosures within 30 days. A change includes a new interest, the elimination of an interest, or a significant change to the nature or value of the interest. Individuals required to disclose must review and update their disclosures as necessary when university roles change, responsibilities change, when new research activities begin, and when there is a change in scope to current research activities. Failure to update disclosures within the 30-day timeframe may result in delays of research funding, a hold on funds, or other mitigation as the result of additional compliance reviews.

Individuals required to disclose are expected to disclose information and comply with any applicable federal or sponsor requirements pertaining to conflicts of interest in their research activities. Compliance with federal requirements includes timely disclosure of all relevant sources of support, including support from foreign entities. Additional policies and procedures related specifically to conflicts of interest in federally sponsored research and projects are required and are outlined in the COI Policy, Appendix A.

The Research COI Committee's disclosure procedures apply to individuals involved in the design, conduct, and reporting of research. Additional review, reporting, and record keeping requirements for Public Health Service of the U.S. Department of Health and Human Services (PHS)-funded research are detailed in Appendix A of the COI Policy.

IV. REVIEW OF RESEARCH

The Research COI Committee (Committee) will consist of a chairperson who will be a CWRU faculty member, and a minimum of three additional faculty members, all of whom will be appointed by the Executive Vice President for Research. The Committee will also include COI staff and additional representatives from the leadership of the Office of Research and Technology Management or their designees. The COI staff, in consultation with the COI Chair, will invite ex-officio committee members to conduct any review of novel or complex conflicts of interest that cannot be resolved by the Committee. Consultants from inside or outside of the university may also be invited, if additional expertise is needed. These members will provide the necessary insight for the review and management of conflicts of interest for specific research and scholarship.

The Committee will convene designated committees for review of human subjects or animal research that involve significant outside financial interests related to research where conflicts require specialized review and management. This specialized review includes, but is not limited to, human subjects research which is being conducted at an affiliate hospital and/or has been determined by the affiliate Institutional Review Board (IRB) or CWRU IRB to be greater-than-minimal risk. The designated committee will include relevant experts who may be faculty, scientists, subject-matter experts, administrators, legal counsel, or other qualified consultants, and they may be from inside or outside the university.

Any Member of the university community with outside interests that are determined to be related to their university responsibilities, including research, may require a management plan. Management plans are written agreements that may impose conditions and prescribe actions necessary, including reduction or elimination of the financial interest. Management plans are developed with the input of the individual and the appropriate committee or university office.

Members of the Committee must recuse themselves from consideration of their own conflicts of interest or conflicts of interest that relate to them.

VI. INSTITUTIONAL COI

An institutional conflict of interest arises when an institution's own financial interests or those of its leadership may appear to or actually distort decisions involving the institution's primary interests. Institutional interests include ownership of intellectual property and equity interests, particularly around start-up or spin-off companies. For university leadership, institutional conflicts can arise from individual outside interests or personal activities. Depending on the nature of the conflict, institutional conflicts of interest will be evaluated and managed by the Board of Trustees or the Research COI Committee.

CORRECTIVE ACTIONS

All members of the university community are expected to understand this policy and their responsibilities related to this policy. The university may take corrective actions for violations of this policy including, but not limited to, appropriate disciplinary action in accordance with university policies and procedures.

APPENDIX A: Additional Requirements for Federally Funded Research

This section outlines the additional requirements that apply to individuals required to disclose who participate in (or plan to participate in) research funded by federal agencies and other funders who follow federal guidelines.

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Federal Agencies Outside of the Public Health Service

The university's research is supported by federal funding from a variety of agencies. Each agency has specific regulations for conflicts of interest in research, and these regulations shift frequently as federal sponsoring agencies revise and update regulations and guidance. The university monitors these changes and shares updates with the university research community as needed. The university's process and disclosure platform are designed to be agile to address changes in these requirements.

Public Health Service of the U.S. Department of Health and Human Services, National Institutes of Health (PHS-NIH)

With regard to research funded by (or 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) and others, 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.

For PHS/NIH-funded research, a financial conflict of interest (FCOI) occurs when an individual has a significant financial interest (SFI) 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.

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.

Training Requirements

All individuals required to disclose will complete training prior to engaging in PHS/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/NIH-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.

Disclosure, Review and Monitoring Requirements

Disclosure must occur at least annually in accordance with the period specified by the university. Typically, an annual disclosure is completed between February and April each year. For those who are listed on a PHS/NIH funding proposal, 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.

Disclosure or confirmation/updating of previously disclosed information also is required at the time a proposal is submitted, and when a research proposal is submitted to relevant review bodies as required.

Review of Disclosures

The Research Conflict of Interests Committee solicits and 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 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.

A significant financial interest (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.

Reporting Requirements to NIH

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, Project Director (PD)/ Principal Investigator (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:

1. The significant financial interest was disclosed and is still held by the senior/key personnel;
2. The university determines that the significant financial interest is related to the PHS-funded research; and
3. The university determines that the significant financial interest is a financial conflict of interest.

Subrecipient Requirements

The university will comply with federal conflict of interest regulations regarding subrecipient agreements, including PHS-funded subrecipient awards. The university is responsible for ensuring any subrecipient's compliance with the regulation and reporting identified FCOI for subrecipient investigators to the NIH. The university will establish via a written agreement whether the university financial conflict of interest policy or that of the subrecipient applies 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 FCOI policy will report identified FCOI to the university in sufficient time to allow the university to report the FCOI to the NIH to meet its reporting obligations.

Subrecipient institutions that must comply with the university's policy must submit all investigator disclosures of SFI 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 FCOI regulation, management plans, and reporting all identified financial conflicts of interest to the NIH.

Mitigation of Noncompliance – 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:

1. failure by the investigator to disclose a significant financial interest that is determined by the institution to constitute a financial conflict of interest;
2. failure by the institution to review or manage such a financial conflict of interest; or
3. 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's 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 and 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.

Maintenance of Records

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 CFR 75.361. The university will retain records for each competitive segment.

APPENDIX B: Definitions

FCOI Investigator – An individual who contributes to the scientific design, conduct, or reporting of PHS-funded research.

Financial conflict of interest (FCOI) – A significant financial interest that could directly and significantly affect the design, conduct or reporting of PHS-funded research.

Institutional responsibilities – 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 – 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 NIH-funded research, or proposed for such funding, and which may include for example, collaborators or consultants. This definition includes investigators who plan to participate in or who participate in NIH-funded research.

Noncompliance - Non-compliance with the provisions of this policy includes, but is not limited to, failing to timely disclose a significant financial or business interest, failing to complete educational requirements, intentionally making an incomplete, erroneous, or misleading report of external activities, failing to provide additional information as required by policy, or failing to follow an approved plan for managing, reducing or eliminating a potential conflict.

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).

Relatedness - Refers to when an investigator’s SFI has any connection with their research.

Senior/key personnel – The Project Director/Principal Investigator and any other person identified as senior/key personnel by the institution in the grant application, progress report, or any other report submitted to the PHS by the institution.

Significant financial interest –

(1) A financial interest consisting of one or more of the following interests of the investigator (and those of the investigator’s spouse and dependent children) that reasonably appears to be related to the investigator’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) in excess of \$5000, upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel in excess of \$5000 (*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 United 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, to determine whether the travel constitutes an FCOI with the PHS-funded research.

Subrecipient - An entity that receives a subaward from a pass-through entity to carry out part of a program; but does not include an individual that is a beneficiary of such program. The subrecipient may be a domestic or foreign educational institution, for-profit or non-profit organization or government. An individual cannot serve as a subrecipient.

Substantial Foreign Relationship - Any relationship between an employee and a program that is sponsored, funded, directed, or controlled by a foreign government, foreign agency, or foreign institution that results in an honorary title; employment; grant support; in-kind support, such as research facilities and equipment; or collaborative patents. Conducting peer review or engaging in an international research collaboration that does not involve a formal relationship with a foreign entity, financial support, or in-kind support are not considered substantial foreign relationships.