

 WHITMAN-WALKER INSTITUTE		Department	CL
		Effective Date	3/28/2018
Policy Title	Financial Conflict of Interest Policy Applicable to PHS-Funded Research Activities	Statutory Authority	45 CFR 50, Subpart F
Approval(s)	Whitman-Walker Institute Executive Director General Counsel		

Purpose The purpose of this policy is to ensure the integrity and objectivity of research at Whitman-Walker Institute and to avoid actual or perceived conflicts, by defining the process for identifying, reporting, and managing potential financial conflicts of interest in research.

Policy Whitman-Walker Institute has a Board-approved Conflict of Interest Policy that applies to each Board member, officer, committee member, and employee of the organization. To ensure the integrity of research, Institute has adopted this Financial Conflict of Interest Policy, intended to supplement that general Conflict of Interest Policy and designed to identify arrangements involving investigators and others who have a financial or fiduciary interest in any outside entity where such arrangements may create risks or the appearance of risks in the conduct and reporting of research.

This policy supports Institute's compliance with the Financial Conflict of Interest Rule promoting objectivity in research funded by the Public Health Service ("PHS"), 42 CFR 50, Subpart F (the "FCOI Rule"). The FCOI Rule establishes standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by the PHS will be free from bias resulting from certain conflicting financial interests.

As a prime grantee or sub-grantee on PHS-funded research grants and sub-grants, Institute is required to ensure that the organization, and particularly any employees or agents who serve as Investigators on PHS-funded research under the direction and control of Institute ("Covered Party"), comply with all aspects of the FCOI Rule.

Definitions **Disclosure of Significant Financial Interests** means an Investigator's disclosure of significant financial interests to an Institution.

Entity means any for-profit or nonprofit organization, whether private or governmental.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI Report means an Institution's report of a Financial Conflict of Interest to a PHS Awarding Component.

Financial Interest means anything of monetary value, whether the value is readily ascertainable.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means Whitman-Walker Institute, Inc., its departments, centers, and any other constituent parts (“Whitman-Walker Institute” or “Institute”).

Institutional Responsibilities means the responsibilities and roles investigators are assigned in the course of their work on behalf of Whitman-Walker Institute. This includes, for example, clinical or professional practice, research, research consultation, teaching, administrative roles, committee service, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

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, or proposed for such funding, which may include, for example, collaborators or consultants.

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

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under the FCOI Rule.

PHS means the 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).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to the FCOI Rule.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. Includes basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). Includes, but is not limited to, any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under the FCOI Rule.

Significant Financial Interest means:

(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), 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, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. Details of this disclosure shall include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with this 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.

(3) The term significant financial interest does **not** include the following types of financial interests: salary, royalties, or other remuneration paid by or on behalf of the Institution to the Investigator if the Investigator is currently employed by or on behalf of or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Procedure A. Submission of Disclosure Form

Investigators shall be required to read, understand, and comply with this Policy and the FCOI Rule. Investigators must disclose financial interests as outlined in this Policy and submit the attached Disclosure Form in connection with PHS-funded research (Attachment A). A Disclosure Form is required to be completed and submitted to the Executive Director of Whitman-Walker Institute or their designee:

1. upon hire;
2. at the time of preparation of any PHS-funded proposal (and before submission of the proposal);
3. at least annually during the period of the award; and
4. when assigned new responsibilities relating to the design, conduct, reporting or administration of research.
5. Additionally, Investigators have an ongoing obligation to disclose any Significant Financial Interest throughout the awarded project period. Investigators must update disclosures of Financial Interests

to Whitman-Walker Institute within thirty (30) days of acquiring or discovering (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest. This includes, but is not limited to, sponsored or reimbursed travel within each 30-day period.

Institute will obtain updated Disclosure Forms from all Investigators every three months via Healthicity Compliance Manager.

B. Training

Investigators are required to complete Whitman-Walker Institute's Conflicts of Interest in PHS-Funded Research training:

- i.** prior to engaging in research related to any PHS/NIH-funded grant, and
- ii.** at least every four years.

Training must also be completed when any of the following occur:

- i.** an Investigator is new to Institute;
- ii.** Institute revises its policy on conflicts of interest in research; or
- iii.** Institute determines that an Investigator is not in compliance with this Policy or their assigned management plan.

As part of such training, Investigators shall be informed of this Policy, the FCOI Rule and their disclosure responsibilities.

The Institute's Executive Director or designee, along with the Senior Director of Research, are principally responsible for ensuring that all Institute employees and agents complete training as required by the FCOI Rule.

C. Prohibitions Designed to Avoid Financial Conflicts of Interest

1. Whitman-Walker Institute has concluded that it in the best interest of the organization to place a cap on the Financial Interest that an Investigator may receive from any one entity. This Policy therefore prohibits Investigators acting on behalf of Institute from receiving a Financial Interest, including but not limited to fees, honoraria, gifts, or "in kind" compensation (or entitlement to same) from any single financially interested entity that is in excess of \$25,000, in the aggregate, during an applicable 12-month reporting period.
2. Institute has also concluded that the acceptance of remuneration by any Investigator acting on behalf of Institute deriving from "product talks", i.e., talks about a specific manufacturer's product or products that may involve the use of a manufacturer's slides, marketing materials or other work product, shall be prohibited under this Policy.

D. Standards for Determining Whether a Financial Conflict of Interest Exists

Any Financial Interest disclosed by an Investigator under this Policy that is determined to be a Significant Financial Interest will be referred to and reviewed by the Institute's General Counsel, who acts as the lead designated official for purposes of reviewing disclosures of Significant Financial Interest under this Policy. 42 CFR 50.604(d).

An Investigator's Significant Financial Interest is related to PHS/NIH-funded research when Whitman-Walker Institute, through its designated official(s), reasonably determines that the Significant Financial Interest:

- could directly and significantly affect the design, conduct, or reporting of the PHS-funded Research; **or**
- is in an entity whose financial interest could be affected by the research.

For this purpose, the term "significant" means the financial interest would have a material effect on the research. If a preliminary determination is made by the lead designated official that a Significant Financial Interest is related to PHS/NIH-funded research, and may be a Financial Conflict of Interest, the potential Financial Conflict of Interest will be reviewed by a Financial Conflict of Interest Committee ("FCOI Committee") comprised of the General Counsel, Executive Director, Senior Director of Research, and any other individuals appointed by the Executive Director. These individuals also act as designated officials under the guidance and leadership of the Institute's General Counsel, who serves as the lead designated official. No Investigator with a potential Financial Conflict of Interest that is under review by the Committee may be a member of the Committee, but such individual may provide the Committee with input on whether a Financial Conflict of Interest exists.

In determining whether a Financial Conflict of Interest exists, the FCOI Committee will consider the nature of the research, the nature and size of the Significant Financial Interest, the degree to which the conflict or potential conflict is related to the research, the extent to which the research could be affected by the Significant Financial Interest, and any means of managing the conflict or potential conflict.

1. Investigators New to Research Projects and Newly Disclosed Significant Financial Interests

When an Investigator who is new to a research project or when an existing Investigator discloses a new Significant Financial Interest, the Institute's designated official(s) shall review the Significant Financial Interest within sixty (60) days, 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 the Financial Conflict of Interest.

2. Significant Financial Interests that Were Not Timely Disclosed, Reviewed or Reported

Should Whitman-Walker Institute identify a Significant Financial Interest that was not timely disclosed by an Investigator or not previously reviewed and/or reported as required, the Institute's designated officials shall review the Significant Financial Interest within sixty (60) days, determine whether a Financial Conflict of Interest exists and, if so, implement, at least on an interim basis, a management plan that shall specify the actions that have been, and will be taken to manage the Financial Conflict of Interest. A memorandum summarizing the FCOI Committee's review and conclusions will be prepared by the Office of General Counsel and maintained in Institute's files in accord with the Maintenance of Records requirements set forth in Section I below.

E. Management of Conflicts

If the FCOI Committee determines that a Financial Conflict of Interest exists that must be managed, the Office of General Counsel shall prepare a proposed plan to manage the Financial Conflict of Interest for review by the Committee ("management plan"). After final approval of the management plan by the Committee, the affected Investigator is required to formally agree to the management plan and sign the written plan before any PHS-sponsored research goes forward. The FCOI Committee will monitor the Investigator's compliance with the plan until completion of the relevant research project.

The management measures or administrative conditions that may be recommended by the FCOI Committee include but are not limited to the following:

1. Public disclosure of the financial interests of the Investigator in all relevant publications, presentations; disclosure to the appropriate co-investigators, members of the laboratory or research group, and students or trainees, and disclosure on human subject consent forms;
2. Placement of any relevant stock in escrow or requiring that options, warrants, and similar instruments not be exercised without the prior permission of the Committee;
3. Limiting the Investigator's role in some way, e.g., the Investigator may not be allowed to serve as Principal Investigator or analyze data or determine whether an adverse event should be reported.
4. Requiring the sale or disposal of specified financial interests to eliminate or reduce the risks associated with the financial interests by a certain date;
5. Requiring severance of relationships that heighten or create actual or potential conflicts, e.g., terminating a consulting arrangement with an outside entity.

In cases where the Committee determines the Significant Financial Interest does not amount to a Financial Conflict of Interest, but the Committee nevertheless believes that the disclosed interest presents a conflict of interest under the Institute's general Conflict of Interest Policy, conflict management measures not otherwise subject to the FCOI Rule or this Policy may be required. The Executive Director of Institute will communicate the FCOI Committee's decision, along with a description of management measures or administrative conditions, to the Investigator or Investigators in writing.

The Executive Director will also inform the Institute Board of Directors and the Audit Committee about the terms of any management plan agreed to by Institute and an Investigator, whether such plan is required under the FCOI Rule or this Policy.

F. External Reporting of Conflicts

Public Accessibility

Institute will make this Policy available to the public via its website and will ensure that the Policy is updated as required under the FCOI Rule.

Institute will also make available to the public within five days of a request the following information with respect to any Financial Conflicts of Interest held by senior/key personnel: (a) the Investigator's name; (b) the Investigator's title and role on the research project; (c) the nature of the Significant Financial Interest; and (d) the approximate dollar value of the Significant Financial Interest within ranges (e.g., \$0-\$4,999; \$5,000-9,999; \$10,000-19,999; \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 in increments of \$50,000), or a statement that the value of the Financial Conflict of Interest cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

The publicly available information concerning identified Financial Conflicts of Interest held by senior/key personnel will be made available within five (5) days of a written request; (2) be updated annually, (3) be updated within sixty (60) days of a new, or newly identified, Financial Conflict of Interest, and (4) remain available for three (3) years from the date the information was most recently added.

Reporting to NIH

Whitman-Walker Institute will submit a Financial Conflict of Interest report to the NIH via the eRA Commons Financial Conflict of Interest Module for Institution and its subrecipients, if applicable, as required under the FCOI Rule: (1) prior to expenditure of PHS/NIH research funds; (2) within sixty (60) days of identification of a Financial Conflict of Interest of an investigator who is new to a research project; (3) within sixty (60) days of a new, or newly identified Financial Conflict of Interest for an existing Investigator, (4) at least annually, in order to provide status of the

Financial Conflict of Interest, any changes to the management plan, etc., and (5) after a retrospective review to update a previously submitted report, if new information is discovered following completion of the review. *See NIH Frequently Asked Question H.5 ("NIH FAQ")*.

Should Whitman-Walker Institute find bias with the design, conduct or reporting of PHS/NIH-funded research, Institute will promptly notify NIH and submit a mitigation report to explain what actions have been or will be taken to mitigate the effects of the bias in accordance with the FCOI Rule. See 42 CFR 50.605(a)(3)(iii). Institute will also notify NIH if an Investigator fails to comply with Institute's Financial Conflict of Interest Policy or a management plan, or whenever corrective action for noncompliance with Institute's Financial Conflict of Interest Policy or a management plan is required.

Whitman-Walker Institute will report to the recipient of the prime PHS award and/or PHS Awarding Component the following information with respect to a Financial Conflict of Interest in connection with PHS-funded research: (a) the Project number; (b) the Program director/principal investigator; (c) the name of the entity in which a Significant Financial Interest is held; (d) the nature of the Significant Financial Interest; (f) the approximate dollar value of the Significant Financial Interest within ranges (e.g., \$0-\$4,999; \$5,000-9,999; \$10,000-19,999; \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 in increments of \$50,000), or a statement that the value of the Interest cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

The report will include a description of how the Financial Conflict of Interest relates to the PHS-funded research and basis for a determination that a Financial Conflict of Interest exists, as well as a specific description of the key elements of the FCOI management plan, including:

1. Role and principal duties of the conflicted Investigator in the research project;
2. Conditions of the management plan;
3. How the management plan is designed to safeguard objectivity in the research project;
4. Confirmation of the Investigator's agreement to the management plan;
5. How the management plan will be monitored to ensure Investigator compliance; and
6. Other information as needed.

A description of how the management plan will be implemented and monitored will also be included in the report. Any changes to the initial FCOI management plan or report must be reported to the PHS Awarding Component.

An annual report on the FCOI management plan must be submitted to the NIH through the eRA Commons FCOI Module each year within a competitive segment or until the Institution reports that the Financial Conflict of Interest no longer exists. The annual Financial Conflict of Interest report will include the following information: 1) status of the Financial Conflict of Interest, and 2) Changes to the FCOI management plan, if applicable.

G. Failures to Comply with Policy and Retrospective Review

A failure to comply with this Policy, including timely, complete, and accurate disclosure of any Significant Financial Interest or the failure to adhere to plans to manage a Financial Conflict of Interest pursuant to this Policy will result in sanctions, including possible termination of employment. If the failure to comply has, or appears to have, biased the design, conduct, or reporting of PHS-funded research, Whitman-Walker Institute will promptly notify the prime recipient of the PHS-funded research and/or the PHS Awarding Component of the findings and corrective action(s) taken or to be taken.

Institute will complete a retrospective review within 120 days of a determination that a Significant Financial Interest was not timely disclosed or reviewed or whenever a Financial Conflict of Interest is not identified or managed in a timely manner. See NIH FAQ, Section I. The retrospective review shall meet all the requirements set forth in 42 CFR 50.605(a)(3).

Should HHS determine that Institution engaged in a research project whose purpose was to evaluate the safety or effectiveness of a drug, medical device, or treatment that was designed, conducted or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by Institution as required by the FCOI Rule, the Investigator with the Financial Conflict of Interest will be required to: (1) disclose the Financial Conflict of Interest in every public presentation of the results of the research, and (2) request an addendum to previously published presentations.

H. Sub-Recipients of PHS-Funded Research

If Whitman-Walker Institute carries out PHS-funded research through a sub-recipient, Institute will either determine that the sub-recipient has its own Financial Conflict of Interest Policy pursuant to 42 C.F.R. Part 50 or will comply with this Policy. If the sub-recipient has adopted its own Financial Conflict of Interest Policy, Institute shall require the sub-recipient to certify that it will abide by its Financial Conflict of Interest Policy.

When Institute carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), Institute must take reasonable steps to ensure that any subrecipient Investigator complies with the FCOI Rule and this Policy by:

(1) Incorporating as part of a written agreement with the subrecipient terms that establish whether this Policy or that of the subrecipient will apply to the subrecipient's Investigators.

(i) If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with the FCOI Rule. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to Institute's Financial Conflict of Interest Policy for disclosing significant financial interests that are directly related to the subrecipient's work for Institute;

(ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to Institute in a timely manner that permits Institute to provide timely Financial Conflict of Interest reports, as necessary, to the PHS as required by the FCOI Rule;

(iii) Alternatively, if the subrecipient specifies that subrecipient's Investigators will comply with Institute's Financial Conflict of Interest Policy, the agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to Institute. The time(s) shall be sufficient to enable Institute to comply timely with its review, management, and reporting obligations under the FCOI Rule and this Policy.

(2) Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with the FCOI Rule prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

I. Maintenance of Records

Whitman-Walker Institute shall maintain all FCOI-related records relating to all Investigator disclosures of financial interests and the Institution's review of, and response, to such disclosures (whether or not a disclosure resulted in Institute's determination of a Financial Conflict of Interest), and all actions under the Institute's FCOI Policy or a retrospective review, if applicable, for a period of at least three (3) years from the date of the final expenditures report to the PHS/NIH or, where applicable, from other dates specified under 45 CFR 75.361.

DocuSigned by: <i>Don Blanchon</i>	7/19/2021
Approval Signature	Date
Don Blanchon, Executive Director	

DocuSigned by: <i>Beth Caseman</i>	7/19/2021
Approval Signature	Date
Beth Caseman, General Counsel	

Originated By: Judy Jenkins, Senior Director of Compliance
Revised By: Beth Caseman, General Counsel
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