PARTNERSHIP
Research Action Health

Partnership for Research and Action for Health (PARTNERSHIP) Policy on Individual Financial Interests and Financial Conflicts of Interest in Research[1]

2020

[1] Developed in line with https://grants.nih.gov/grants/policy/coi/index.htm, and adapted from the State University of New York Downstate Health Sciences University Research Conflict of Interest Policy (https://www.downstate.edu/coi/documents/coi_policy_v9.12.2020.pdf)

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I Introduction

Partnership for Research and Action for Health (PARTNERSHIP) is not-for profit, non-governmental organization registered in Georgia in 2006. The activities of the organization are based on conducting research in the field of public health and attaining scientific-research evidence and serves to promote the improvement of population health and support the reform of health policies and systems.

The mission of the PARTNERSHIP is to promote population health through implementation of high quality research, educational, and service efforts on the problems of public health and health management in Georgia and beyond its boundaries.

The PARTNERSHIP's vision is to be recognized as one of the leading public health research institution in Eastern European region.

As an institution devoted to public health research, and education, and service we have the following core values and commitments:

- Dedication to excellence to create the best possible research evidence
- Dedication to our continuous development as educators
- An inclusive and respectful environment for all staff, partners, and stakeholders
- Continuous efforts towards internationalization
- Shared commitment to improved health for all
- Multidisciplinary approach in addressing health challenges in a society
- Engagement with partners at local, regional, national, and global level
- Commitment to the principles of the ethical practice of public health.

II Purpose

In June 2020, the PARTNERSHIP initiated implementation of the new grant project "Strategic Training PARTNERSHIP to End AIDS in Georgia". The 5-year project is supported by the United States Department of Health and Human Services (DHSS), National Institutes of Health (NIH), Fogarty International Center (FIC). The aim of the project is to address the HIV care continuum gaps through training the next generation of Georgian scientists in public health and implementation science. As an institution entrusted with public funds received from the Government of Georgia as well as from governments of other countries including the United States Government (USG) to carry out its research and educational missions, the PARTNERSHIP must ensure that its activities are conducted in an ethical, transparent, and bias-free environment to maintain the public trust. In conjunction with the PARTNERSHIP's Conflict of Interest Policy (COI) and Code of Conduct, PARTNERSHIP's Research COI Policy is in place to guide Investigators in their everyday work, to outline required and prohibited conduct, and to provide guidance on how actual or perceived COI can be managed so as to enable industry and commercial PARTNERSHIPs, which are essential to advance our missions.

III Policy

It is PARTNERSHIP's policy that Investigators may not have any interest, financial or otherwise, direct or indirect, or engage in business, transactions or professional activities or incur obligations of any nature that is in conflict with the proper discharge of their duties in the best interests of the PARTNERSHIP or that can be reasonably expected to bias the design, conduct or reporting of research unless these conflicts are appropriately declared and properly managed in accordance with the procedures and guidelines outlined below. Investigators must disclose their interests and outside activities, and those of a related party, which may affect their independent and objective performance of their duties.

IV Definitions[2]

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

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 or not 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 any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: 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 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, consultants or doctoral students and their mentors conducting PHS-supported research.

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 this subpart.

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 this subpart.

Outside Activity means any outside business or employment activity including: (A) ownership or investment in any outside business or enterprise, (B) serving as a director, officer, partner, consultant, broker, agent, or representative of any outside enterprise; (C) outside professional activity or other activity; or (D) other employment.

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. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes 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

[2] In line with https://ecfr.io/Title-42/Section-50.603

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.

Related means an Investigator's significant financial interest is related to the research or activity when the PRAH designated official reasonably determines that the significant financial interest could be affected by the funded research or is an entity whose financial interest could be affected by the research.

Related Party means spouse and/or dependent child of an Investigator.

Remuneration includes salary and any payment for services not otherwise identified as salary (such as consulting fees, honoraria, paid authorship). Remuneration excludes 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; and income from seminars, lectures or teaching engagements sponsored by and service on advisory or review panels for a Federal, State or local government agency, an institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education.

Senior/key personnel means the PD/PI 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 under this subpart.

Significant financial interest **(SFI)** means 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;
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> (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 (IP) rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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.

Sponsored Travel includes any reimbursed or sponsored travel related to the Investigator's institutional responsibilities (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). This does not apply to travel that is reimbursed by a Federal, State or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. Disclosures are required once the $5,000 threshold in value of travel from a single non-exempt entity has been reached.

V Responsibilities

Responsible Party	Responsibility
FCOI Committee	• Appoint the FCOI Committee Chair. • Develop and implement management plans to manage FCOI. • Complete retrospective reviews of Investigator's activities and research projects (within one hundred twenty (120) days of a determination of non- compliance in identifying/managing a FCOI) to determine whether there was bias in the design, conduct or reporting of such research. • Complete Research Compliance training program, as required.
Finance and Administration Unit Designee	• Serves as the FCOI Officer responsible for FCOI administration. • Provides support, guidance and training for the establishment of the FCOI administrative processes, contributes to the establishment of policies and procedures associated with Federal and State regulations. Provides highly efficient and seamless customer service to the research community at PARTNERSHIP. • Takes a leadership position in the establishment of the electronic disclosure form tracking system and workflow procedures (within the PARTNERSHIP's organizational SharePoint). • Coordinates the review and processing of the FCOI Disclosure Forms for Investigators to meet submission requirements of: 1) Submission with Application for Grant /Award/Project, 2) New Disclosures submissions, and 3) Annual Disclosures submissions. • Coordinates and plans all FCOI training activities for the Responsible Parties, including Investigators, FCOI Committee and Administration at PARTNERSHIP. • Assists FCOI Committee with the development of policies and training programs that ensure adherence to Federal mandates on research compliance, works with applicable parties to develop campus-wide implementation plans. • Monitors Federal and State regulation and related compliance issues concerning FCOI and provides written interpretations of the potential impact to PARTNERSHIP research operations.

	• Provides advice and counsel on risk management issues to the FCOI Chairperson and Committee concerning the results of the evaluation of the submitted Financial COI Disclosure Forms. • Provides research and analysis via Internet and other publicly available information sources to determine and or verify potential relationships of significant financial interest to better inform the Chair and Committee evaluation process. • In the event that a FCOI is determined to exist, the FCOI Administrator will coordinate and document the Committee's prescribed management plan that specifies actions to be performed by the Investigator and provide the appropriate follow up for the Committee. Coordinates the communication to the CEO and/or Designee to perform any required actions to protocols or grant activity. • Responsible to develop and distribute metrics on FCOI Disclosure Form submissions and documentation of Investigator's successful completion of FCOI training to the Chair and the Committee. • As needed, assists in responding to public requests for FCOI information in accordance with current PHS regulations. • Runs reports to determine if annual disclosure forms were submitted. • Notifies and follows up with individuals who have not submitted the form.
Institutional Review Board	• Ensure that IRB approval is not granted unless all applicable disclosures have been reported and reviewed for the IRB applications described above. • Review approved management plans for a project to determine if any additional protections are necessary for research participants.
Investigators (as defined above)	• Complete PARTNERSHIP's Annual Disclosure Questionnaire on an annual basis. • Complete PARTNERSHIP's Transactional Questionnaire at the time of submission of an application for an award/ grant/ study/ project. • Complete PARTNERSHIP's Transactional Questionnaire when submitting any of the following documents to the IRB: o Initial IRB Application of the following types, when submitting an application at least 30 days after the submission date of Annual Disclosure Questionnaire: ▪ Expedited Review ▪ Convened (Full) IRB Review ▪ External IRB Review ▪ Exempt IRB Review for FDA Regulated or Federally Funded/ Conducted Research o An amendment to be added to the IRB application (Full Board or Expedited review only) o An Application for Progress Report (Continuing IRB) when the progress report is required by the IRB. • Revise Annual Questionnaire within thirty (30) days of discovering a new SFI.

	• Submit confirmation or rebuttal of management plans within thirty (30) days and comply with final, binding management plan. • Certify compliance with management plan, as necessary. • Disclose reimbursed or sponsored travel related to research and/or institutional responsibilities as specified in the policy. • Complete Research Compliance training program, as required.
Principal Investigator	• Properly identify Investigator roles on studies submitted to the IRB Office and/or Research Administration Office of Sponsored Programs Office. • See additional responsibilities delineated under "Investigators."
CEO and/or Designee	• Appoints and maintain a FCOI Committee. • Ensures that relevant research staff and affiliated investigators comply with the FCOI policy and file the appropriate disclosure form(s), as necessary. • Ensures relevant research staff and affiliated investigators comply with required management plans, when requested. • Reviews rebuttals of management plans and make final, binding determination within thirty (30) days. • Institutes disciplinary proceedings against an Investigator, when necessary.
Research Administration Unit Designee	• Ensure an application for grant or contract funding has all applicable disclosure forms and FCOI training (completed within 4 years) on file for all Investigators. • Place flags on grants that have a management plan for the Investigator in the proposal file of record. • Determine at the time of proposal whether sub-recipients have their own PHS-compliant policy or will instead follow PARTNERSHIP's Research FCOI Policy. If the latter, assure that disclosures have been made prior to the subaward being issued and/or funds being expended. • At the time of award, incorporate into sub-recipient agreements which FCOI policy will apply and ensure sub-recipient certification of compliance is received before agreement is finalized either by (1) receiving an individual certification or (2) by documenting that the sub-recipient has provided its certification of institutional compliance with PHS FCOI requirements in the Federal Demonstration Partnership (FDP) Institutional Clearinghouse or (3) incorporating PARTNERSHIP's Research FCOI policy in the terms of the sub-award. • Make the necessary certifications of compliance with the FCOI requirements in each grant or contract proposal, individually or via the FDP Institutional Clearinghouse, for all activity supported by PHS or organizations that follow the PHS policy. • Review pertinent Investigator disclosures related to foreign influence pursuant to regulatory requirements. • Place holds on accounts that have management plans to prevent expenditure of funds until a FCOI Report is submitted

	or until confirmation of the approved management plan is received. • Upload to NIH applicable Management Plans via eRA Commons. • Check to confirm that all Investigators on a research project have submitted disclosures and completed training at time of award setup, including at-risk awards, and when out-year funds are authorized or supplemental funds extending the life of award are received; release holds on accounts once compliance is verified. • Place flags on grants that have a management plan for the Investigator in the award file of record.

VI Procedures/Guidelines

A. Submission of Financial COI Disclosure Form

Disclosures are required in four instances:

- Annual Disclosures: The Disclosure form for all Investigators must be submitted on an annual basis.
- Submission of Grant/Award: Investigators are required to submit the PARTNERSHIP Transactional Disclosure Form prior to award/account set up for a sponsor grant or award.
- Submission of an IRB Protocol for Human Research: Investigators are required to submit the PARTNERSHIP Annual and/or Transactional Disclosure Forms at the time of submission.
- New Disclosures: An updated Disclosure Form must be submitted within thirty (30) days of a new Outside Activity or interest that falls under this policy.

1. On an annual basis, an updated Disclosure form must be filed for each Investigator.
2. At the time of submission of a study to the IRB Office, the Principal Investigator is responsible for identifying all Investigators and designating their role on the IRB registration form. This will enable the IRB to flag the application for COI purposes.
3. All Investigators are required to submit the PARTNERSHIP Disclosure form describing their external activities and significant financial interests (SFI), as well as those of their Related Parties, that reasonably appear to be related to the individual's institutional responsibilities.
4. The PARTNERSHIP Disclosure form must be submitted via the electronic disclosure filing system (i.e., PARTNERSHIP's organizational SharePoint).
5. The PARTNERSHIP will not submit any proposal for grant/contract funding unless all of the Investigators named in the proposal have submitted a Disclosure form in the electronic system. The IRB will review the protocol and will not provide IRB study approval unless all of the Investigators named in the proposal have submitted a Disclosure form and have received FCOI review approval. The latter is applicable for all Federal and non-Federal studies. However, non-federal exempt studies (as defined by IRB policies) are excluded from the FCOI requirements.
6. Initial and out-year award funding and project extensions will not be released until annual disclosures have been filed for all Investigators, including those who have been added to the project since the proposal or most recent progress report was submitted, and all Investigators are in compliance with FCOI training requirements.
7. The FCOI Administrator will routinely run management reports to determine those members who have not submitted an Annual Disclosure form and will notify the individual and/or chair, as necessary.
8. Whenever SFI's, external activities or internal responsibilities change materially from those described in the Disclosure form, the individual is required to submit an updated Annual Disclosure form as soon as possible and no later than thirty (30) days from discovering or acquiring the new SFI.

B. Review of Financial COI Disclosure Form

The PARTNERSHIP is responsible for reviewing the SFI's documented in the Disclosure form to determine whether these interests relate to the Investigator's research programs and objectives; including disclosures of any foreign influence. This review will be conducted upon receipt of the Annual Disclosure form and again upon receipt of the Transactional Disclosure, which occurs in tandem with the proposal or protocol submission. A SFI is related to the research when it is reasonably determined that the research could be affected by the SFI or an outside activity may potentially compromise the objective performance of the individual's professional duties.

1. For all disclosed SFI's, both the relatedness determination and the FCOI analysis will be performed by the FCOI Administrator.
2. The assessment will require access to the funding application, progress reports, and any other technical and programmatic documentation, and may also require scientific expertise in order to understand whether the aims of a specific project affect the identified SFI's or the financial interests of the disclosed entities would be affected by the research. The following methods will be utilized:
    a. A scientist from a related field may be included in making the relatedness determination;
    b. The company sponsors or manufacturers listed in the grant/protocol will be reviewed to determine whether they are a wholly owned subsidiary or direct competitor of the companies listed in the Disclosure form;
    c. If only drug compounds are listed, without an associated manufacturer, the compounds will be reviewed to determine whether they reflect a drug that is marketed or licensed by a company represented on the Disclosure form;
    d. The relatedness determination will include an assessment of the nature of the research and/or business activities of the SFI related entity as they may relate to the Investigator's academic programs or objectives.
3. The rationale supporting the relatedness determination will be documented and maintained by the Conflicts of Interest Administrator.

C. Financial COI Analysis & Development of Management Plans

1. If the Investigator's SFI's are determined to be related to the research, a FCOI analysis must be performed. A FCOI exists when it is reasonably determined that the SFI could directly and significantly affect the design, conduct or reporting of the research or when the Investigator's activities on behalf of a SFI-related entity relate to the Investigator's PARTNERSHIP research programs, scholarly duties or intellectual property.
2. If a FCOI is determined to exist, the FCOI Administrator, FCOI Chair and/or FCOI Committee will develop and implement a management plan that specifies the actions that have been/will be taken to manage such FCOI's. Examples include:
    a. Public disclosure of FCOI's (e.g., before presenting or publishing the research and disclosing commercial relationships to trainees such as students, technicians and postdocs);
    b. For research projects involving human subject research, disclosure of the FCOI's directly to the participants (e.g., in the IRB study Consent Form);
    c. Appointment of an independent committee to oversee and monitor the educational goals and progress of students performing research at a commercial facility as part of their degree training;
    d. Appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of the research against bias resulting from the FCOI (this is often the Chair);
    e. Modification of the research plan(s);

f. Change of personnel or personnel responsibilities or disqualification of personnel from participation;
g. Review of ongoing/ future intellectual property (IP) development to identify potential conflicts that may emerge between academic and new IP commercialized entities that come into existence;
h. Prohibiting the PI from influencing PARTNERSHIP's purchasing decisions;
i. PI's requirement to disclose and receive approval for not- insignificant use of shared resources (for example, lab space, equipment, supplies and staff).

3. Should the previous actions be insufficient, there will be an evaluation as to whether:

a. Reduction or elimination of the financial interest; or, in rare instances;

b. Severance of relationships that create financial conflict are necessary to address the conflict.

4. The FCOI Administrator will ensure an executed copy of the management plan is available in the electronic disclosure filing system and will make additional details available to the following parties, as necessary:

a. The PARTNERSHIP's CEO;
b. Institutional Review Board;
c. Research Administration Unit;

5. The Research Administration Unit, and the Institutional Review Board (when applicable) will place a flag on the grant/contract/project to indicate the presence of a management plan.

6. Within thirty (30) days of receipt of a management plan, the Investigator is required to submit the following to the FCOI Administrator/ Chair:

Either:

a. Indication of acceptance/ approval of the management plan- the Investigator should electronically submit the approval;

Or:

b. Specific requested revisions to the management plan;

i. The FCOI Administrator, FCOI Chair and/or FCOI Committee will evaluate the requested revisions and if appropriate, prepare a revised management plan within thirty (30) days for the Investigator's review;

ii. Within fifteen (15) days of receipt of the revised plan, the Investigator will either indicate acceptance/ approval of the revision or proceed with the rebuttal process as specified below.

iii. If no revisions are deemed appropriate, the Investigator will have fifteen (15) days of receipt of such decision to either accept/ approve the original management plan or proceed with the rebuttal process specified below.

c. Rebuttal of the management plan:

i. If the Investigator rebuts the management plan, it will be sent, along with the Investigator's specific requested changes, to the CEO and/or Designee for reconsideration.

ii. The CEO and/or Designee will make a determination within thirty (30) days and submit the determination in writing to the Investigator.

iii. The management plan approved by the CEO and/or Designee is final and binding. The Investigator is required to immediately abide by the terms of this plan.

If the Investigator neither accepts the management plan nor submits requested submissions or a rebuttal within thirty (30) days of receipt of the management plan, the management plan will default to "Accepted/ Approved" and the Investigator will be required to abide by its requirements.

7. The Finance Unit will place a hold on the account to prevent any expenditure of funds.

a. For PHS funded research, or for research that is funded by sponsors that adhere to PHS FCOI regulations, the hold will not be removed until the submission of the FCOI Report.

b. For all other research, the hold will be removed when an approved/confirmed

management plan is on file.

D. Submission of FCOI Reports (this policy section currently applies only to PHS Awards)

Prior to PARTNERSHIP's expenditure of funds under a PHS funded research project, the FCOI Administrator will submit to the PHS awarding agency an Initial FCOI Report regarding the Investigator's SFI's determined to be conflicting and the management plan implemented. In cases where a FCOI was identified but was eliminated prior to the expenditure of funds, a FCOI Report will not be submitted.

1. The Initial FCOI Report will include sufficient information to enable the PHS awarding agency to understand the nature and extent of the financial conflict, as well as to assess the appropriateness of the management plan. The following elements will be included in the report:

a. Project/Contract number;
b. Principal Investigator/Contact Principal Investigator;
c. Name of Investigator with the financial COI;
d. Name of the entity with which the Investigator has a financial COI;
e. Nature of the financial interest (Ex: Equity, consulting fee, travel reimbursement, honorarium);
f. Value of the financial interest (May include dollar ranges as follows: $0- $4,999; $5,000- $9,999; $10,000- $19,999; amounts between $20,000- $100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
g. A description of how the financial interest relates to the PHS funded research and the basis for PARTNERSHIP's determination that the financial interest conflicts with such research;
and
h. A description of the key elements of PARTNERSHIP's management plan, including:
    i. Role and principal duties of the conflicted Investigator in the research project;
    ii. Conditions of the management plan;
    iii. How the management plan is designed to safeguard objectivity in the research project;
    iv. Confirmation of the Investigator's agreement to the management plan;
    v. How the management plan will be monitored to ensure Investigator compliance;
    vi. Other information, as needed.

2. Once the Initial FCOI Report has been submitted, the FCOI Administrator will notify the Finance and Research Administration Units to remove the hold on the Investigator's account and allow funding expenditures or will notify the IRB Office so that it can move forward with protocol review and approval.

3. For each project that required the submission of an Initial FCOI Report, an Annual FCOI Report that addresses the status of the FCOI and any changes to the management plan will be submitted on an annual basis.

a. The Annual FCOI Report will specify whether the FCOI is still being managed or will explain why the FCOI no longer exists.
b. Annual FCOI Reports will be submitted for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS awarding agency.

E. New Disclosures of SFI

If, during the course of an ongoing PHS funded or otherwise funded project, an Investigator who is new to participating in the research project discloses a SFI or an existing Investigator discloses a new SFI, or there is new information regarding a SFI that was not disclosed timely or not previously reviewed, the FCOI Administrator will, within sixty (60) days:

1. Review the disclosure of the SFI;
2. Determine whether the SFI is related to the research;
3. Determine whether a FCOI exists;
4. If so, implement, on at least an interim basis, a management plan that specifies the actions that have been/ will be taken to manage the FCOI.

F. Retrospective Reviews and Mitigation Reports

If there is information regarding a SFI that was not identified or managed in a timely manner, including failure by the Investigator to disclose a SFI determined by the PARTNERSHIP to constitute a FCOI, failure by the PARTNERSHIP to review or manage the FCOI or failure by the Investigator to comply with the FCOI management plan, the FCOI Committee will, within one hundred twenty (120) days of the PARTNERSHIP's determination of non- compliance, complete a retrospective review of the Investigator's activities and the research project to determine whether any research, or portion thereof, conducted during the time period of the non-compliance, was biased in the design, conduct or reporting of such research.

1. A determination of bias may be difficult to determine. However, the following metrics may be utilized:
    a. Reviewing enrollment to determine whether inclusion/exclusion criteria have been met;
    b. Looking at systemic protocol deviations for irregularities that might indicate that scientific integrity was undermined;
    c. Assessing whether the design of the study was suspect.
2. The research staff associated with the project may be interviewed to determine whether there were any intentional or unintentional instances of misinterpreting data.
3. The retrospective review will be documented with the following elements:
    a. Project number;
    b. Project title;
    c. Principal Investigator or Contact Principal Investigator;
    d. Name of the Investigator with the FCOI;
    e. Name of the entity with which the Investigator has a FCOI;
    f. Reason(s) for the retrospective review;
    g. Detailed methodology used for retrospective review (Ex: Methodology of the review process, composition of the review panel, documents reviewed);
    h. Findings of the review; and
    i. Conclusions of the review.
4. Based upon the results of the retrospective review, if appropriate, the FCOI Administrator will update previously submitted FCOI reports and specify the actions taken to manage the FCOI going forward.
5. If a determination of bias is made, the FCOI Administrator will promptly prepare and submit a Mitigation Report to the PHS awarding agency. The Mitigation Report will include the following:
    a. Elements included in retrospective review, as delineated above;
    b. A description of the impact of the bias on the research project; and
    c. PARTNERSHIP's plan of action(s) taken to eliminate or mitigate the effect of the bias (Ex: 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).
6. Thereafter, the FCOI Administrator will submit FCOI reports on an annual basis.
7. Depending upon the nature of the FCOI, the FCOI Committee may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the FCOI or the Investigator's non- compliance was determined and the completion of the retrospective review.

G. Public Transparency (this policy section currently applies only to PHS Awards)

1. The FCOI Administrator will respond to any written request, within five (5) business days from the date the FCOI Administrator receives the request, of information concerning any SFI disclosed to PARTNERSHIP that meet the following criteria:
    a. The SFI was disclosed and is still held by Investigator;
    b. The FCOI Administrator/ FCOI Committee determined that the SFI is related to the research; and
    c. The FCOI Administrator/ FCOI Committee determined that the SFI is a FCOI.
2. The information provided to the requestor will include the following:
    a. The Investigator's name;
    b. The Investigator's title and role with respect to the research project;
    c. The name of the entity in which the SFI is held;
    d. The nature of the SFI; and
    e. The approximate dollar value of the SFI or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
3. This Information will be maintained for a period of three (3) years from the date that the information was most recently updated.

H. Travel

Investigators receiving PHS funding must disclose all reimbursed or sponsored travel related to their research and/or institutional responsibilities when the aggregated value exceeds $5,000 per entity. This disclosure requirement does not apply to travel that is reimbursed or sponsored by: (1) a Federal, State or local government agency; (2) an institution of higher education; (3) an academic teaching hospital; (4) a medical center or a research institute that is affiliated with an institution of higher education.

1. The following information must be provided for all covered travel:
    a. Identity of the sponsor/organizer;
    b. Destination;
    c. Duration;
    d. Purpose of trip;
    e. Relationship to institutional responsibilities; and
    f. Estimated dollar value of expenses.
2. The FCOI Administrator is responsible for reviewing the Investigator's travel related to the research and determining whether it directly or significantly affects the design, conduct or reporting of the research, constituting a FCOI. The following potential red flags will be utilized to make FCOI determinations:
    a. International travel;
    b. Inclusion of an Investigator's spouse or family;
    c. Travel that appears unnecessary in terms of location, duration or scheduled recreational activities;
    d. Travel for a duration beyond typical timeframes necessary for the intended purpose of the travel;
    e. Many trips from one entity in a short period of time.
3. Travel determined to be a FCOI will be referred to the FCOI Committee for review and development of a management plan, if necessary.

I. Sub-Recipient Requirements Regarding FCOI Policies

For PHS funded research and for research funded by organizations that follow PHS policy that is carried out through a sub-recipient, the PARTNERSHIP will incorporate into a written agreement the

terms that establish whether the FCOI policy of the PARTNERSHIP or that of the sub-recipient will apply to the sub-recipient's Investigators.

1. If the sub-recipient's Investigators are required to comply with their own FCOI policy, the sub-recipient must either be registered in the FDP Institutional Clearinghouse, or submit a certification as part of the agreement that its policy complies with the Federal requirements.
    a. The PARTNESRHIP will not finalize the agreement until this certification has been documented.
    b. If the sub-recipient's Investigators are required to comply with their own FCOI policy, the agreement will specify that the sub- recipient report all identified FCOI's to the PARTNERSHIP's FCOI Administrator: (1) At the time of the initial agreement execution, prior to expenditure of funds; (2) On an annual basis; and (3) Within thirty (30) days of any subsequently identified SFI.
    c. Subject to review and approval by the Office of Sponsored Programs and the FCOI Administrator - Sub-recipients who cannot provide such certification, or who have not registered in the FDP Institutional Clearinghouse may be subject to PARTNERSHIP's COI policy and may be required to disclose SFI's directly related to the sub-recipient's work for PARTNERSHIP.
2. If the sub-recipient's Investigators are required to comply with the PARTNERSHIP's FCOI policy, the agreement will specify the following time- periods for the sub- recipient to report all identified FCOI's to the PARTNERSHIP's FCOI Administrator: (1) At the time of the initial agreement execution, prior to expenditure of funds; (2) On an annual basis; and (3) Within thirty (30) days of any subsequently identified SFI.

J. Consultant or Collaborator Requirements Regarding COI Policies

For PHS funded research and for research funded by organizations that follow PHS policy that is carried out with the participation of a non-PARTNERSHIP consultant or collaborator who meets the definition of Investigator, the consultant or collaborator will follow the PARTNERSHIP's FCOI Policy and provide disclosures and complete the online training (available at www.citiprogram.org) in the same time-frame as the PARTNERSHIP investigators, if the consultant/ collaborator does not have his/her own FCOI policy. These individuals will be subject to the PARTNERSHIP's FCOI management plan, when applicable.

K. Education

The PARTNERSHIP will educate its Investigators, and any others who come under the PARTNERSHIP's policies, on the FCOI policy and Investigators' responsibilities regarding disclosure of SFI's and complying with the regulations.

1. Investigators will be required to complete the online FCOI training program (available at www.citiprogram.org) under the following circumstances:
    a. Upon hire;
    b. Prior to engaging in research related activities;
    c. Routinely every four (4) years;
    d. If the PARTNERSHIP determines that an Investigator is not in compliance with the FCOI policy or a particular management plan.
2. The Finance and Administration Unit will coordinate the provision of such training to the Investigators, in accordance with the PARTNERSHIP's policy, "Compliance Training."

L. Administrative Requirements

1. The PARTNERSHIP will maintain an up- to- date, written and enforced FCOI policy, in compliance with applicable requirements, which will be available on its public website.
2. The PARTNERSHIP will maintain adequate enforcement mechanisms for the FCOI policy.

3. The PARTNERSHIP will maintain the following records for a period of three (3) years from the date of final payment, unless another requirement applies to retain the information for a longer time frame:

a. All Investigators' disclosures of financial interest;
b. The PARTNERSHIP's review of and response to such disclosures, whether or not the disclosure resulted in a management plan;
c. All the PARTNERSHIP actions under the FCOI policy;
d. All retrospective reviews.

4. The PARTNERSHIP will certify when required by the sponsor, in the grant/contract proposal that it:

a. Has in effect an up- to- date, written and enforced administrative process to identify and manage FCOI's with respect to all research projects for which funding is sought or received from Federal sources;
b. Shall promote and enforce Investigator compliance with these requirements, including those that pertain to disclosure of SFI's;
c. Shall manage FCOI's and provide initial and ongoing FCOI reports to the PHS awarding agency consistent with the requirements;
d. Agrees to make information available, promptly upon request, to the Department of Health and Human Services (HHS) relating to any Investigator disclosure of financial interests and the PARTNERSHIP's review of, and response to, such disclosure, whether or not the disclosure resulted in the PARTNERSHIP's determination of a FCOI; and
e. Shall comply fully with the COI requirements.

M. Non- Compliance

1. All instances in which an Investigator has failed to comply with this FCOI policy or a FCOI management plan appears to have biased the design, conduct or reporting of the research must be reported immediately to the FCOI Administrator. The FCOI Administrator will consult with the CEO and/or Designee, the Research Administration Unit, and IRB Offices to determine appropriate corrective actions.
2. In cases where disciplinary action is necessary and depending on the facts and circumstances of each case, the CEO and/or Designee may take one or more of the following actions, in compliance with the applicable collective bargaining agreements and the PARTNERSHIP's policies:

a. Reprimand;
b. Probation or other alteration of employment/academic status with the PARTNERSHIP;
c. Suspension;
d. Dismissal/Termination;
e. Referral for criminal prosecution; and/or
f. Demand of reimbursement to the PARTNERSHIP for any losses or damages resulting from the failure to comply with this FCOI policy.

3. Upon completion of the disciplinary proceedings, the FCOI Administrator will report to the appropriate parties and to the applicable PHS agencies when PHS funds are involved.
4. The PARTNERSHIP will comply with any further action required by the PHS agencies on how to maintain appropriate objectivity in PHS funded research projects, including suspending the research project, if required.
5. In any case in which HHS determines that a PHS funded project of clinical research whose purpose is to evaluate the safety and effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with a FCOI that was not managed or reported by the PARTNERSHIP, as required, the PARTNERSHIP shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations. Similar action will be taken if a FCOI was not managed or reported by the PARTNERSHIP if the research is non-funded or funded by a non-PHS organization that implements PHS FCOI requirements.

VII Resources used

- Instructions for submitting an FCOI Policy into eRA Commons IPF Module (10/1/2020) – (PDF) – This document provides the instructions for submitting the institution's financial conflict of interest (FCOI) policy in the eRA Commons IPF Module per NIH Guide Notice NOT-OD-21-002 "Required Submission of Financial Conflict of Interest Policy into the eRA Commons Institution Profile (IPF) Module" dated 9/30/2020.
- FCOI Policy Development Checklist (4/24/2020) – (PDF) - An overview of the FCOI regulation to serve as a resource when developing, revising or reviewing an Institution's FCOI policy to determine compliance with all regulatory requirements. [MS Word version - 37 KB]. Initially posted on 4/12/2012.
- FCOI Noncompliance Reporting Requirements Summary Chart – (8/21/2012) - (MS Word) - Summary of the reporting requirements when there is an instance of noncompliance with the FCOI regulation
- Financial Conflict of Interest Presentation with Case Studies (06/26/2012) - (PowerPoint - 13.4 MB) - These slides provide an overview of the Federal FCOI regulation provided at 42 CFR Part 50, Subpart F on *Promoting Objectivity in Research* that was presented at the NIH Regional Seminar in Washington, DC on June 22, 2012.
- What NIH Grantees Need to Know About the 2011 Revised Financial Conflict of Interest Regulation: *Webinar, November 30, 2011, 2-3:30pm EST.*
    - Archive
    - FCOI Webinar PowerPoint Slides (PowerPoint - 7.3 MB)
    - FCOI Webinar PowerPoint Slides (PDF - 2.5 MB)
- NIH Guide Notices Related to Financial Conflict of Interest.