



Subject: Financial Conflict of Interest

Division: Grants Management

Date: 5/29/13

FINANCIAL CONFLICT OF INTEREST POLICY AND PROCEDURES

Purpose of Policy

The purpose of COG Analytics' (hereinafter referred to as COG) Financial Conflict of Interest (FCOI) Policy is to comply with Federal regulation 42 CFR Part 50 Subpart F and to protect COG, its employees, its clients, and research participants from potential or actual risks associated with any financial conflicts of interest related to PHS-funded research studies conducted by Investigators.

Purpose of Federal Regulation 42 CFR Part 50 Subpart F

The purpose of this regulation is to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants and cooperative agreements will be biased by any conflicting financial interest of an Investigator.

Application of Policy

This policy applies to all Investigators (including subrecipient investigators) and key personnel who are planning to participate in or are participating in Public Health Service (PHS) funded research. Compliance with this policy is a condition of employment and/or relationship with COG.

An "Investigator" is defined as 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 PHS (e.g., National Institutes of Health (NIH)), or proposed for such funding, including persons who are subgrantees, contractors, consortium participants, collaborators or consultants. Note, that these responsibilities are not limited to the Project Director, Principal Investigator, or key personnel but rather, apply to all individuals who are responsible for the design, conduct, or reporting of research. COG will consider the role, rather than the title, of those individuals involved in research and the degree of independence with which they work.

All covered persons are hereinafter referred to as "Investigator."

Training Requirements

Investigators are required to complete FCOI training:

1. Prior to engaging in research related to any PHS-funded grant,
2. At least every 4 years, and
3. Immediately, if:
 - COG revises its FCOI policy and procedures in any manner that affects Investigator requirements;
 - An Investigator is new to COG; and/or
 - An Investigator is not in compliance with the policy or management plan.

Please see FCOI required training at: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

Financial Conflict of Interest (FCOI)

An FCOI exists when COG, through its FCOI Officer, reasonably determines that an Investigator (including their spouse and dependent children) has a Significant Financial Interest (SFI) related to a NIH-funded research project that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

Significant Financial Interest (SFI)

Investigators are required to disclose to COG a listing of SFIs (and those of his/her spouse and dependent children) that: (1) would reasonably appear to be affected by the research for which funding is sought, and (2) includes those entities whose financial interests would reasonably appear to be affected by the research.

PHS FCOI regulation defines a “Significant Financial Interest” as follows:

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:
 - a. 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 etc.); 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;
 - b. 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

- c. 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 by 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. COG'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 COG's FCOI policy, the FCOI Officer 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 regarding 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 COG to the Investigator, if the Investigator is currently employed or otherwise appointed by COG;
 - any ownership interests in COG, if COG is an applicant under the SBIR and STTR programs;
 - Intellectual property rights assigned to COG and agreements to share in royalties related to such rights;
 - Any ownership interest 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 by 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;
 - income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education as defined by 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.

Disclosure of a SFI

An Investigator is under a continuing obligation to disclose any SFI (and those of his/her spouse and dependent children), or the appearance of a financial conflict, as soon as it is known, or reasonably should have been known.

The SFI must be disclosed to COG: 1) by the time an application is submitted to NIH for funding; 2) within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI; and 3) on an annual basis at intervals determined by COG.

An Investigator shall complete the attached SFI Disclosure Form in order to fully disclose a SFI. The SFI Disclosure Form shall be completed upon first participation in a PHS award with COG, and shall be updated annually, thereafter, prior to each new PHS award year. An additional SFI Disclosure Form shall be filed to COG within 30 days of discovering or acquiring a new SFI.

All disclosures of SFI shall be sent to COG and will be reviewed by COG's FCOI Officer. The COG FCOI Officer shall send his/her personal SFI Disclosure Form to the COG Management Committee for review.

Procedures for Review of an Actual or Potential FCOI

When there is reason to believe that an actual or potential FCOI exists, or the appearance of an FCOI exists, between the interests of COG and that of an Investigator, the COG Management Committee shall ultimately be responsible for determining the appropriate response. This shall include, but not necessarily be limited to, invoking the procedures described below with respect to a specific proposed action.

Where the appearance of a SFI or an actual or potential SFI involves an Investigator, the FCOI Officer shall review the matter and determine whether an Investigator's SFI is related to PHS-funded research and if so related, whether the SFI is an FCOI. The FCOI Officer will notify the COG Management Committee, who will take appropriate action to protect the interests of COG, its employees, and its clients and research participants. The FCOI Officer shall report his/her determinations and suggestions for management of the conflict to the COG Management Committee for review and adjudication.

The Managing Partner of COG shall serve as the FCOI Officer in reviewing actual or potential conflicts of interest in those cases in which the COG FCOI Officer has a potential FCOI or there exists the appearance of an FCOI.

Procedures for Addressing an FCOI

Where an actual or potential FCOI exists or the appearance of an FCOI exists, COG shall refrain from making any decisions concerning the FCOI until the COG Management Committee has reviewed the FCOI and approved the action. The following procedures shall also apply:

- An Investigator who has an actual or potential FCOI or the appearance of an FCOI shall not participate in, or be present during, the deliberations and decision-making with respect to this action unless requested by the COG Management Committee, and then will be present only to answer questions, provide information about the alleged FCOI, or respond to proposed COG actions.
- The COG Management Committee may approve the proposed actions for remediation or amelioration of the FCOI upon a finding that these actions are in the best interests of COG, its employees, clients, and/or research participants.
- The meeting minutes shall reflect that the FCOI was discussed, the nature of the Committee's decision, and that a vote was taken regarding that decision.

- Members of the COG Management Committee must recuse themselves from any discussion and vote on issues in which they have an FCOI or appear to have an FCOI.

Management of FCOIs

COG will make every effort to ensure that FCOIs do not bias research conducted by Investigators and that do not place clients, research participants, or others at risk.

If the COG Management Committee determines that an FCOI exists or has the potential to exist, it shall determine what conditions or restrictions, if any, should be imposed by COG to manage these actual or potential conflicts.

Examples of conditions or restrictions that might be imposed by the COG Management Committee to manage FCOIs include, but are not limited to: 1) Public disclosure of SFIs; 2) Monitoring and Management of the FCOI by the COG FCOI Officer; 3) Review of the research protocol by independent reviewers; 4) Monitoring of the research by independent reviewers; 5) Modifications of the research plan; 6) Disqualification of the Investigator from participation in all or a portion of the research funded by PHS or NIH; 7) Divestiture of significant financial interests; and/or 8) Severance of relationships that create actual or potential conflicts of interest.

If the COG Management Committee does impose conditions or restrictions upon an Investigator with respect to managing an FCOI, a management plan shall be prepared that details the conditions or restrictions imposed upon the Investigator in the conduct of the project or regarding their relationship with COG. The management plan shall be signed by the Investigator and the Managing Partner of COG. Actual or potential conflicts of interests will be satisfactorily managed, reduced, or eliminated, and/or they will be disclosed to the sponsoring agency for action.

If the COG Management Committee determines that imposing the above-referenced conditions or restrictions would be inequitable, or that the potential negative impacts that may arise from a SFI are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the COG Management Committee may determine that the research should go forward without imposing such conditions or restrictions, although an Investigator would still need to disclose the nature of the conflict on a yearly basis (see Disclosure of Actual or Potential FCOI, above).

Compliance monitoring of the SFI will occur through a yearly review of the management plan by the FCOI Officer, resulting in subsequent recommendations to the COG Management Committee. Based on Investigator compliance, the COG Management Committee may decide to maintain, reduce, or eliminate the ongoing compliance monitoring plan. Or, the COG Management Committee may impose additional conditions or restrictions upon an Investigator, as outlined above.

Procedures for Review of an Actual or Potential FCOI by the IRB

When there is reason to believe that an actual or potential FCOI exists, or the appearance of an FCOI exists, between the interests of COG and that of an Investigator, and involves research reviewed by the Institutional Review Board (IRB), the IRB will be notified. The FCOI Officer will send the IRB a report of his/her assessment of the real or perceived FCOI. He/she will send a remediation plan regarding any FCOI to the IRB.

Investigators should disclose any FCOI to the IRB at the time of the Initial Application for a research protocol review, at the time of Continuing Review, or whenever the status of the FCOI changes. The IRB Administrator shall report any new or modified FCOI issues to the COG FCOI Officer, who will share that report with the COG Management Committee.

The IRB will review Investigator disclosures and the FCOI Officer's assessment of any FCOI, taking particular note of the impact of the FCOI on research integrity and risks to research participants. The IRB will make the final decision about the FCOI at a convened meeting and may require the following:

1. Prohibition of Investigators' participation in the research;
2. Management of the FCOI through:
 - Disclosure to research participants or others regarding the FCOI, as part of the consenting process;
 - Public disclosure in published articles, forums and presentations;
 - Limiting the role of the Investigators;
 - External oversight of the study by an oversight entity outside of COG;
 - Investigators deciding to sever relationships with those organizations, persons, entities, or interests that present an FCOI, or appear to present an FCOI;
 - Other remediation, as required.

Reporting Requirements to NIH

Prior to COG's expenditure of any funds under a NIH-funded research project, COG will provide to NIH an FCOI report regarding any Investigator SFI found by COG to be an FCOI, in accordance with the regulation. COG will also provide an FCOI report to NIH whenever an Investigator fails to timely disclose a SFI or whenever COG designated staff, for whatever reason, fail to timely review and/or properly identify a disclosed SFI but then subsequently review and determine that an FCOI exists. COG must report all identified FCOIs to NIH.

COG will submit an FCOI report to NIH within sixty (60) days after its determination that an FCOI exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new SFI to COG during the award period.

Whenever an Investigator does not timely disclose a previously existing SFI or COG designated staff fail to timely review and/or properly identify a previously existing SFI regarding an ongoing NIH-funded project, COG's designated staff shall, within sixty (60) days: 1) review the SFI; 2) determine whether it is related to the NIH-funded research; and 3) determine whether an FCOI exists. And, if so, COG will implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage such an FCOI going forward and submit an FCOI report to NIH.

In addition to the FCOI report, COG will, within 120 days of COG's determination of noncompliance, complete a retrospective review of the Investigator's research activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of noncompliance, was biased in the design, conduct or reporting of such research.

Based on the results of the retrospective review, if appropriate, COG designated staff will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

If bias is found, COG designated staff will notify NIH officials promptly and submit a mitigation report that includes the key elements documented in the retrospective review and a description of the impact of the bias on the research project and COG's action plan or actions taken to eliminate or mitigate the effects of the bias. Thereafter, COG will submit FCOI reports annually.

COG will notify NIH promptly if an Investigator fails to comply with COG's FCOI policy or if the FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research.

For any FCOI previously reported by COG, the Managing Partner shall provide an annual FCOI report to NIH that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Annual FCOI reports will be submitted to NIH for the duration of the project period (including extensions with or without funds) at the same time as when COG is required to submit the annual progress report (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of the extension (e.g., submission of an extension notification in eRA Commons or submission of a NIH prior approval request, whichever is applicable.) An annual FCOI report is not to be submitted as part of the annual progress report. The annual FCOI report is submitted to NIH separately through the eRA Commons FCOI Module at the same time the annual progress report is submitted.

Reporting Requirements to the Food and Drug Administration

The Food and Drug Administration (FDA) requires Investigators to certify the absence of and/or disclose the existence of any FCOI. For more information, please see the following website:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=54.4>

Reporting Requirements to Sponsors

Investigators should contact the sponsors of research in which they are participating to determine their requirements regarding any FCOI.

Violations of the FCOI Policy

If the COG Management Committee has reason to believe that an Investigator has failed to disclose an actual or potential FCOI, or the appearance of an FCOI, the COG Management Committee shall inform that Investigator of the basis for this belief and allow him/her an opportunity to respond.

If, after hearing the response of the Investigator, documentation of the response, and after initiating further investigation (as required), the COG Management Committee, in determining that the Investigator has failed to disclose an actual or possible FCOI, or the appearance of an

FCOI, shall take appropriate administrative, disciplinary and/or corrective actions, such as implementing employee sanctions to ensure Investigator compliance.

In any case in which the Department of Health and Human Services (DHHS) determines that an NIH-funded clinical research project, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator in which there was a financial conflict of interest that was not managed or reported by COG as required by the regulation, COG will require the Investigator(s) involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

Subrecipient Investigator Requirements

COG will incorporate language, as part of a written agreement with a subrecipient that the FCOI Policy of the subrecipient will apply to the subrecipient's Investigator. The subrecipient must provide COG with certification that the subrecipient Investigator is in compliance with 42 CFR Part 50 Subpart F and must submit all Investigator reported SFIs to COG within 30 days of discovering or acquiring a new SFI or, at the very least, in sufficient time for COG to meet its FCOI reporting obligations. If a subrecipient does not have an FCOI Policy that complies with 42 CFR Part 50 Subpart F, a subrecipient Investigator must follow COG's FCOI Policy in all aspects.

Maintenance of Records

All FCOI-related records will be retained for at least 3 years from the date that the final expenditure report is submitted to PHS. Documents will also be retained from the dates specified in 45 CFR 74.53(b) and 92.42(b), where applicable.

Public Accessibility

The COG FCOI policy is publically available on COG's website.

Prior to COG's expenditure of any funds under a NIH-funded research project, COG shall ensure public accessibility, via COG's publicly accessible website located at www.coganalytics.com or by a written response to any requestor within 5 business days of a request, of information concerning any SFI disclosed to COG that meets the following three criteria:

1. The SFI was disclosed and is still maintained by COG senior/key personnel regarding a NIH-funded research project;
2. COG determines that the SFI is related to the NIH-funded research; and
3. COG determines that the SFI is an FCOI.

The information that COG makes available via its publicly accessible website or written response to any requestor shall include, at a minimum, the information listed in the PHS regulations at 42 CFR 50.605(a)(5)(ii), including:

- a. Investigator's name;
- b. Investigator's title and role with respect to the research project;
- c. Name of the entity in which the SFI is held;
- d. Nature of the SFI; and

- e. Approximate dollar value of the SFI (dollar ranges are permissible: \$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.

COG Financial Conflict of Interest Officer

Steven B. Carswell, Ph.D.
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Significant Financial Interest (SFI) Disclosure Form

PHS application/FOA Number:	Grant Title:			PD/PI (Last, first, middle):
Investigator's Name (Last, first, middle):	Name of Organization/Institution:	Office Phone:	Date of Disclosure:	Date FCOI Training Received:
Title: <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Co-Investigator <input type="checkbox"/> Collaborator <input type="checkbox"/> Subrecipient Investigator <input type="checkbox"/> Consultant <input type="checkbox"/> Other (Specify)				

Assets and sources of earned income that reasonably appear to be related to your professional responsibilities on behalf of COG:

- Identify for you, your spouse and dependent children: 1) assets with a fair market value of \$5,000 at the close of the reporting period; and 2) sources of earned income which generated over \$5,000 in income during the reporting period. For additional information, please refer to the attached definitions page.

Part I: ASSETS

Assets include stocks, bonds, tax shelters, pensions, annuities, real estate, commodity futures, trades and business and partnership interests that reasonably appear to be related to your professional responsibilities in behalf of COG.

I do not have any assets requiring disclosure to COG.

I hereby disclose the following assets:

Name of Asset(s)	Asset belongs to (Employee, Spouse or Dependent Child, or combination):	(X) if no longer held:	Asset Type (pension, stock, dividends, interest, real estate, capital gains):	Please provide the approximate dollar range(s) of the SFI <u>only</u> if the remuneration from an entity or equity interest in the entity exceeds \$5,000 when aggregated.			
				\$0 - \$4,999 increments of \$1,000 (e.g.\$1,000 to 2,000)	\$5,000 - \$19,999 increments of \$5,000 (e.g. \$5,000 to \$10,000)	\$20,000 - \$100,000 increments of \$20,000	\$100,000 and above by increments of \$50,000
1.		<input type="checkbox"/>		\$	\$	\$	\$
2.		<input type="checkbox"/>		\$	\$	\$	\$
3.		<input type="checkbox"/>		\$	\$	\$	\$
4.		<input type="checkbox"/>		\$	\$	\$	\$

Part II: SOURCES OF EARNED INCOME AND TRAVEL

Sources of earned income include; salaries received from other than your current employer, fees, honoraria, and travel that reasonably appear to be related to your professional responsibilities on behalf of COG.

I do not have Sources of Earned Income requiring disclosure to COG.

I hereby disclose the following assets:

Name of Earned Income Source(s)	Income Recipient (Employee, Spouse or Dependent Child, or combination):	Income Type (salary, consultant fees, honoraria, etc.):	Please provide the approximate dollar range(s) of the SFI <u>only</u> if the remuneration from an entity or equity interest in the entity exceeds \$5,000 when aggregated.			
			\$0 - \$4,999 increments of \$1,000 (e.g.\$1,000 to 2,000)	\$5,000 - \$19,999 increments of \$5,000 (e.g. \$5,000 to \$10,000)	\$20,000 - \$100,000 Increments of \$20,000	\$100,000 and above by increments of \$50,000
1.			\$	\$	\$	\$
2.			\$	\$	\$	\$
3.			\$	\$	\$	\$

For travel disclosures, please include the following detail; purpose of the trip, identity of the sponsor, destination and duration that reasonably appear to be related to your professional responsibilities on behalf of COG.

Travel Sponsor	Destination	Duration	Purpose
1.			
2.			

You are required to submit an updated SFI disclosure form to COG within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI. Based on the training that I have received, I certify that the statements I have provided on this form are true, complete, and correct to the best of my knowledge.

Investigator Signature: _____	Date: _____	COG FCOI Officer Signature: _____	Date: _____
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SFI Disclosure Form Definitions as provided by the Office of Extramural Research of the National Institutes of Health

Significant Financial Interest (SFI) is defined by the regulation as:

- (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**:
 - a. With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock options, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - b. With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) hold any equity interest (e.g., stock, stock options, or other ownership interest); or
 - c. 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. The Investigator's disclosure will include the identity of the sponsor/organizer, the destination, and the duration. COG can request additional information from the Investigator in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
- (3) The term SFI **does not** include the following types of financial interests:
 - a. Salary, royalties, or other remuneration paid by the Institution (i.e., Investigator's employer) to the Investigator, if the Investigator is currently employed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
 - b. Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
 - c. 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;
 - d. 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;
 - e. 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.

KEY DEFINITIONS

Agreement - COG's grant, cooperative agreement, subcontract, or contract for a Public Health Service (PHS) research project.

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

Financial Interest - anything of monetary value, whether or not the value is readily ascertainable, including remuneration, salary, other payments for services (e.g., consulting fees, paid authorship or honoraria), equity interests (e.g., stocks, stock options, or other ownership interest), intellectual property rights (e.g., patents, copyrights, and royalties from such rights), and reimbursed or sponsored travel unless the sponsored travel is paid for 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.

Institutional Responsibilities - an Investigator's professional responsibilities on behalf of COG which include: research activities, 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, principal investigator, or subrecipient investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of a PHS research project (research funded by the NIH), or proposed for such funding, which may include, for example, subgrantees, contractors, consortium participants, collaborators or consultants.

Significant Financial Interest (SFI) - one or more of Investigator Financial Interests (and those of the Investigator's spouse and dependent children) *that reasonably appears related to the Investigator's institutional responsibilities*, and where the value of such Investigator Financial Interest exceeds \$5,000, existing at the date of SFI disclosure and going back 12 months. SFI *does not* include: (1) salary, royalties, or other remuneration from FRI, (2) salary, royalties, or other payments from any source other than COG that, when aggregated for the Investigator and spouse and dependent children in the 12 months preceding disclosure, are not expected to exceed \$5,000, (3) income from seminars, lectures, or teaching engagements, service on advisory committees or review panels sponsored by federal, state or local government agencies, 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 as defined at 20 U.S.C. 1001(a), (4) an equity interest that, when aggregated for the Investigator/Project Director and spouse and dependent children, does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, or (5) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not control such fund's or account's investment decisions.

Subrecipient - any party that has entered into an agreement with COG as a subgrantee, subcontractor, collaborator, contractor, or consultant.