



FRIENDS RESEARCH INSTITUTE, INC.
1040 Park Avenue, Suite 103
Baltimore, MD 21201

Subject: Financial Conflict of Interest
Division: Grants Management
Date: August 24, 2012, rev. 3/14/13, rev. 6/15/16

FINANCIAL CONFLICT OF INTEREST POLICY AND PROCEDURES

Purpose of Policy

The purpose of Friends Research Institute's (FRI) Financial Conflict of Interest (FCOI) Policy is to comply with Federal regulation 42 CFR Part 50 Subpart F and to protect FRI, its employees, its clients, and its 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 applicable research staff 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 FRI.

All covered persons (Investigators and applicable research staff) are hereinafter referred to as "Investigator."

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. FRI will consider the role, rather than the title, of those individuals involved in research and the degree of independence with which they work.

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:
 - FRI revises its FCOI policy and procedures in any manner that affects Investigator requirements;
 - An Investigator is new to FRI; 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 FRI, 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 FRI 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. FRI'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 FRI'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 FRI to the Investigator, if the Investigator is currently employed or otherwise appointed by FRI;
 - any ownership interests in FRI, if FRI is an applicant under the SBIR and STTR programs;

- Intellectual property rights assigned to FRI 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 FRI: 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 FRI.

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 FRI and shall be updated annually. An additional SFI Disclosure Form shall be submitted to FRI within 30 days of discovering or acquiring a new SFI.

All disclosures of SFI shall be sent to FRI and will be reviewed by FRI's FCOI Officer. The FRI FCOI Officer shall send his/her personal SFI Disclosure Form to the President of FRI 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 FRI and that of an Investigator, the President 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 President, who will take appropriate action to protect the interests of FRI, its employees, its clients, and its research participants. The FCOI Officer shall report his/her determinations and suggestions for management of the conflict to the President for review and adjudication. The President may discuss these determinations with the Executive Management Committee (EMC), which consists of the President, Vice President, Medical Director, and Chief Operating Officer of FRI, who may render an opinion to the President regarding further specialty review or action. The President shall, at his/her discretion, report his/her determination to the Chairman of the Board of Directors, who in consultation with the Executive Committee of the Board of Directors, shall determine if any further Board review or action is required.

In addition, the President will present a report of all FCOI cases at the Board of Directors' meetings.

The President of FRI shall serve as the FCOI Officer in reviewing actual or potential conflicts of interest in those cases in which the FRI 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, FRI shall refrain from making any decisions concerning the FCOI until the President has reviewed the FCOI and approved the action, or has presented the FCOI to the Board of Directors. 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 President or Board of Directors, and then will be present only to answer questions, provide information about the alleged FCOI, or respond to proposed FRI actions.
- The President may approve the proposed actions for remediation or amelioration of the FCOI upon a finding that these actions are in the best interests of FRI, its employees, its clients, and/or its research participants.
- If a finding of an FCOI, or a decision about an FCOI, is to be determined by the Board of Directors, determination and/or approval by the members of the Board shall be by a majority vote, at a convened meeting, at which a quorum is present. The Investigator who is the subject of the FCOI shall not be present during the vote.
- The meeting minutes shall reflect that the FCOI was discussed, the nature of the Board's decision, and that a vote was taken regarding that decision.
- Members of the Board of Directors 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

FRI 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 President determines that an FCOI exists or has the potential to exist, he shall determine what conditions or restrictions, if any, should be imposed by FRI to manage these actual or potential conflicts.

Examples of conditions or restrictions that might be imposed by the President of FRI to manage FCOIs include, but are not limited to: 1) Public disclosure of SFIs; 2) Monitoring and Management of the FCOI by the FRI 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 President of FRI 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 FRI. The management plan shall be signed by the Investigator and the President of FRI. 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 President of FRI 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 President of FRI 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 President. Based on Investigator compliance, the President may decide to maintain, reduce, or eliminate the ongoing compliance monitoring plan. Or, the President may impose additional conditions or restrictions upon an Investigator, as outlined above. In addition, the President may discuss the outcome of the review with the EMC, who may render an opinion to the President regarding further specialty review or action. Moreover, the President shall, at his/her discretion, report such information to the Chairman of the Board of Directors, who in consultation with the Executive Committee of the Board of Directors, shall determine if further Board review or action is required.

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 FRI 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 FRI 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 FRI FCOI Officer, who will share that report with the President, the EMC, and the Grants Management Department.

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 FRI;
 - 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 FRI's expenditure of any funds under a NIH-funded research project, FRI will provide to NIH an FCOI report regarding any Investigator SFI found by FRI to be an FCOI, in accordance with the regulation. FRI will also provide an FCOI report to NIH whenever an Investigator fails to timely disclose a SFI or whenever FRI 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. FRI must report all identified FCOIs to NIH.

FRI 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 the Institution during the award period.

Whenever an Investigator does not timely disclose a previously existing SFI or FRI designated staff fail to timely review and/or properly identify a previously existing SFI regarding an ongoing NIH-funded project, FRI'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, FRI 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, the Institution will, within 120 days of FRI'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, FRI 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, FRI 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 FRI's action plan or actions taken to eliminate or mitigate the effects of the bias. Thereafter, FRI will submit FCOI reports annually.

FRI will notify NIH promptly if an Investigator fails to comply with FRI'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 FRI, FRI 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 FRI 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.ecfr.gov/cgi-bin/text-idx?SID=9f1ef0695db15fe908ba2512fa9d78d5&mc=true&node=pt21.1.54&rqn=div5>

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 President has reason to believe that an Investigator has failed to disclose an actual or potential FCOI, or the appearance of an FCOI, the President 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 President, 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 the Institution as required by the regulation, FRI 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

FRI will incorporate language, as part of a written agreement with the subrecipient, that the FCOI Policy of the subrecipient will apply to the subrecipient's Investigator. The subrecipient must provide FRI with certification that the subrecipient Investigator is in compliance with 42 CFR Part 50 Subpart F and must submit all Investigator reported SFIs to FRI within 30 days of discovering or acquiring a new SFI or, at the very least, in sufficient time for FRI 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 FRI's FCOI Policy in all aspects.

Maintenance of Records

All FCOI-related records will be retained for at least 3 years from the date 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 FRI FCOI policy is publically available on FRI's website.

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

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

The information that FRI 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.

FRI Financial Conflict of Interest Officer

Steven B. Carswell, Ph.D.
1040 Park Avenue, Suite 103
Baltimore, MD 21201
410-837-3977 ext. 252
Email: scarswell@friendsresearch.org

Significant Financial Interest (SFI) Certification Form

Name:	Name of Organization/Institution:	Position Title:
Phone Number:	Email Address:	Date FCOI Training Received:

Certification questions below should be answered "YES" only if ALL of the following criteria are met:

- **The financial interest belongs to you, your spouse, and/or dependent child(ren);**
- **The financial interest reasonably appears to be related to your institutional responsibilities on behalf of FRI; AND**
- **The financial interest may have the perceived potential to directly and significantly affect the design, conduct, or reporting of research.**

The following DO NOT require disclosure:

- Financial interests that do not reasonably appear to be related to your institutional responsibilities;
- Salary, royalties, or other remuneration paid to you by FRI;
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency; a U.S. Institution of higher education or an associated research institute, a medical center, or an academic teaching hospital;
- Income for services (e.g., honoraria, advisory committees, and review panels) and travel expenses paid by a federal, state, or local government agency; a U.S. Institution of higher education or an associated research institute, a medical center, or an academic teaching hospital;
- Income from investments in mutual funds or retirement accounts, as long as you do not directly control the investment decisions made in these vehicles (for example, an interest in a pooled fund); and
- SBIR and STTR Program Phase I awards to small businesses, if applicable

Certification Questions

- Yes No 1. Have you or your immediate family member(s) received remuneration (e.g., non-FRI salary or payment for other services such as consulting, honoraria, paid authorship/book royalties) from a publicly traded entity that, when aggregated over the past 12 months, exceeds \$5,000?
- Yes No 2. Do you or your immediate family member(s) own stock in a publicly traded company, where the value of the stock exceeds \$5,000 at the time of this certification?
- Yes No 3. Do you or your immediate family member(s) receive a combination of the above two items (stock at the time of certification and income received in the preceding 12 months) that exceeds \$5,000?
- Yes No 4. Do you or your immediate family member(s) currently hold any amount of equity (stock, stock options, or other ownership interest) in a non-publicly traded entity, including a startup company?
- Yes No 5. Have you or your immediate family member(s) received remuneration from a non-publicly traded entity that, when aggregated over the past 12 months, exceeds \$5,000?
- Yes No 6. Do you or your immediate family member(s) serve as director, trustee, officer, or other key employee in a for-profit corporation, partnership, business, or other entity outside of FRI?
- Yes No 7. Do you or your immediate family member(s) receive income from licensed intellectual property rights and interests (e.g., patents, copyrights) in excess of \$5,000 related to such rights and interests?
- Yes No 8. Do you or your immediate family member(s) participate in reimbursed or sponsored travel (not including travel reimbursed or sponsored by a government agency or an institution of higher education)?

For any "YES" answers, complete the Significant Financial Interest (SFI) Disclosure Form and attached it to this form.

Signature:	Date:
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FCOI Office Review (For Internal Use Only)

- No financial or fiduciary relationships disclosed; or the financial interest does not meet the SFI threshold.
- The relationship disclosed represents a significant financial interest (SFI).
- The SFI disclosed may be reasonably related to the research regarding grant number(s):
- The SFI is determined to **not** be a Financial Conflict of Interest.
- The SFI is determined to be a Financial Conflict of Interest that requires additional management.
- FRI is required to report the FCOI to the funding agency.

FRI 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. FRI 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 - FRI'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 FRI 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 FRI 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 FRI as a subgrantee, subcontractor, collaborator, contractor, or consultant.