



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

Subject: Conflict of Interest
Division: Board of Directors
Date: February 15, 2013 (revised)

CONFLICT OF INTEREST POLICY AND PROCEDURES

Purpose of Policy

The Purpose of Friends Research Institute's (FRI) Conflict of Interest (COI) Policy is to protect FRI, its employees, and its clients and research participants from potential or actual risks related to any conflicts of interest.

Application of Policy

The Board of Directors, Advisory Board members, IRB members, Investigators, employees of FRI, consultants, interns, and volunteers are covered by this policy. All covered persons are hereinafter referred to as "FRI Associates."

Conflict of Interest (COI)

A COI exists when the interests of an FRI Associate or his/her relative, significant other, or business affiliate/relationship appear to compete, or do compete, with the interests of FRI. There are a variety of situations that raise COI concerns, including (but not limited to) the following:

1. **Financial Interests** - A COI may exist where an FRI Associate or his/her relative (including spouse and/or dependent children), significant other, or business affiliate/relationship obtains a financial benefit that would not have been obtained absent the FRI Associate's relationship with FRI.

Examples include:

- FRI contracts to purchase or lease goods, services, or property from an FRI Associate or his/her relative, significant other, or business affiliate/relationship;
- FRI purchases an ownership interest in, or invests in, a business entity owned by an FRI Associate or his/her relative, significant other, or business affiliate/relationship;
- FRI offers employment to an FRI Associate's relative, significant other, or business affiliate/relationship;
- An FRI Associate or his/her relative, significant other, or business affiliate/relationship is provided with a gift, gratuity or favor of a substantial nature (a value exceeding \$100.00) from a person or entity that does business or seeks to do business with FRI;

- An FRI Associate or his/her relative, significant other, or business affiliate/relationship is provided free or below-market use of the facilities, property, or services of FRI.
- **Bidding** - FRI will obtain competitive bids for all goods, property, or services in excess of \$1,000. If an FRI Associate or his/her relative, significant other or business affiliate/relationship presents the lowest bid, it may be accepted, provided that the FRI Associate did not have prior knowledge of the pricing or technical specifics of the bids of competitors, and the potential or actual conflict of interest of the FRI Associate was disclosed to the President, Vice President, or Chief Operating Officer. This policy does not mandate that the lowest bid be chosen. It serves to create an equal opportunity for all potential vendors.

Investigators

Investigators are required to disclose to a designated FRI official(s) a listing of Significant Financial Interests (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.

A “Significant Financial Interest” is defined by Health and Human Services (HHS) as follows:

- A. 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:
 - 1) 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;
 - 2) 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
 - 3) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- B. 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.

C. 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.

Note: Investigators are required to refer to FRI's Financial Conflict of Interest Policy and Procedures and to complete the Significant Financial Disclosure Form before beginning work on any PHS-funded research study.

2. **Other Interests** – A COI may exist where an FRI Associate or his/her relative, significant other, or business affiliate/relationship obtains a non-financial benefit that would not have been obtained absent the FRI Associate's relationship with FRI, or where an FRI Associate's duty or responsibility to FRI conflicts with a duty or responsibility to some other person, organization, or interest.

Examples include:

- An FRI Associate seeks to obtain preferential treatment by FRI for him/herself, his/her relative, significant other, or business affiliate/relationship, or some other organization or entity;

- An FRI Associate seeks to use confidential or proprietary information obtained from FRI for his/her own benefit, or for the benefit of his/her relative, significant other, or business affiliate/relationship, or some other organization or entity;
 - An FRI Associate seeks to take advantage of an opportunity, or enables a relative, significant other, business affiliate/relationship or other organization or entity to take advantage of an opportunity, which the FRI Associate knows, or should have known, would be of interest to FRI.
3. **Use of FRI Services, Property & Facilities** - A COI may exist where an FRI Associate or his/her relative, significant other, or business affiliate/relationship obtains, *without authorization* from the FRI President or designated FRI official(s), benefit(s) from the use of any FRI service, property, or facilities that would not have been obtained absent the FRI Associate's relationship with FRI.

Examples include:

- Service - laboratory testing, IT assistance, treatment or counseling, secretarial help, telephone or computer time, etc.
 - Property - supplies, software, disposables, consumables (i.e., medical, scientific and pharmaceutical supplies, food, beverages), etc.
 - Facilities - real property or real estate, rental or sales discounts, fees or commissions, use of FRI facility space, etc.
4. **Proprietary or Confidential Information** - A COI may exist where an FRI Associate or his/her relative, significant other, or business affiliate/relationship uses for monetary and non-monetary gain or profit, *without authorization* from the FRI President and Board of Directors, any proprietary or confidential information, in any way, that would not have been obtained absent the FRI Associate's relationship with FRI.

Examples include:

- data, results, reports, notes, records, information, methods, processes, trade secrets, intellectual property, etc.

Disclosure of Actual or Potential COI

An FRI Associate is under a continuing obligation to disclose any actual or potential COI, or the appearance of a conflict, as soon as it is known, or reasonably should have been known.

An FRI Associate shall complete the attached *Disclosure Form* to fully disclose any actual or potential COI, or the appearance of a COI. The disclosure statement shall be completed upon first association with FRI, and shall be updated annually, thereafter. An additional disclosure statement shall be filed, using the *Disclosure Form*, when any new, potential or actual conflict or appearance of a conflict arises.

All disclosures of COI shall be sent to the FRI COI Officer at 1040 Park Avenue, Suite 103, Baltimore, MD 21201. The FRI COI Officer shall send his/her personal disclosure form to the President of FRI.

Procedures for Review of Actual or Potential COI

When there is reason to believe that an actual or potential COI exists, or the appearance of a conflict of interest exists, between the interests of FRI and that of an FRI Associate, 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 COI or an actual or potential COI involves an FRI Associate, the Conflict of Interest Officer shall review the matter and notify the President, who will take appropriate action to protect the interests of FRI, its employees, and its clients and research participants. The COI 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 Conflict of Interest cases at Executive Committee meetings and Board of Directors' meetings.

The President of FRI shall serve as the Conflict of Interest Officer in reviewing actual or potential conflicts of interest in those cases in which the COI Officer has a potential COI or there exists the appearance of a COI.

Procedures for Addressing a COI

Where an actual or potential COI exists, or the appearance of a COI exists, FRI shall refrain from making any decisions concerning the COI until the President has reviewed the COI and approved the action, or has presented the COI to the Board of Directors. The following procedures shall also apply:

- An FRI Associate who has an actual or potential COI or the appearance of a COI, 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 COI, or respond to proposed FRI actions.
- The President may approve the proposed actions for remediation or amelioration of the COI upon a finding that these actions are in the best interests of FRI, its employees, or its clients or research participants.
- If a finding of a COI, or a decision about a COI, 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 FRI Associate who is the subject of the COI shall not be present during the vote.

The meeting minutes shall reflect that the COI was discussed, the nature of the Board's decision, and that a vote was taken on that decision.

Members of the Board of Directors must absent themselves from any discussion and vote on issues in which they have a COI or appear to have a COI.

Additional Requirements for Investigators

FRI will make every effort to ensure that conflicts of interest do not bias research conducted by FRI Investigators and staff and do not place clients, research participants, or others at risk.

Reporting Requirements for COI to the IRB and the FRI COI Officer

- Investigators should disclose any COI to the IRB and the Conflict of Interest Officer.
- The COI Officer will send the IRB a report of his/her assessment of the real or perceived COI. He/she will send a remediation plan regarding any COI to the IRB.
- Investigators should disclose any COI to the FRI IRB at the time of the Initial Application for a research protocol review, its Continuing Review, or whenever the status of the COI changes. The IRB administrator shall report any new or modified COI data or issues to the FRI COI Officer, who will share that report with the Institutional Official and President.
- The IRB will review the Investigators' disclosures and the Conflict of Interest Officer's assessment of any COI, taking particular note of the impact of the COI on research integrity and risks to research participants.
- The IRB will make the final decision about the COI and may require the following:
 - (1) Prohibition of the Investigators' participation in the research;
 - (2) Management of the COI through:
 - Disclosure to research participants or others regarding the COI, 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 a conflict of interest, or appear to present a COI;
 - Other remediation, as required.

External Reporting Requirements

- **FDA**: The FDA requires Investigators to certify the absence of and/or disclose the existence of any financial COI. See the following website:

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

- **NIH and NSF**: The NIH and NSF require Investigators to disclose any COI to their NIH or NSF Grants Management Officer at the NIH Institute funding the project, or the NSF headquarters.
- **Other Sponsors**: Investigators should contact the sponsors of research in which they are participating to determine their requirements regarding any COI.

Violations of COI Policy

If the President has reason to believe that an FRI Associate has failed to disclose an actual or potential COI, or the appearance of a COI, the President shall inform that Associate of the basis for this belief and allow him/her an opportunity to explain.

If, after hearing the response of the FRI Associate, documentation of the response, and pursuing further investigation (as required) the President, in determining that the FRI Associate has failed to disclose an actual or possible COI, or the appearance of a COI, shall take appropriate administrative, disciplinary, and/or corrective actions.

FRI Conflict of Interest Officer

Steven B. Carswell, Ph.D.
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410-837-3977 ext. 252
Email: scarswell@friendsresearch.org



FRIENDS RESEARCH INSTITUTE, INC.
Conflict of Interest Disclosure Form

This Disclosure Form should be completed only after a careful reading of the FRI Conflict of Interest Policy. Please fill out this form as accurately and completely as possible. Please mail the completed form to Friends Research Institute, 1040 Park Avenue, Suite 103, Baltimore, Maryland 21201, or fax to 410-752-4218. All forms will be reviewed by the Conflict of Interest Officer.

Name of FRI Associate: _____

Association with FRI: _____

I declare that the following Conflict(s) of Interest or the appearance of a Conflict(s) of Interest exists:

1. Financial Interests Yes No

If Yes, explain: _____

2. Other Interests Yes No

If Yes, explain: _____

3. Use of FRI Services, Property, and Facilities Yes No

If Yes, explain: _____

4. Proprietary or Confidential Information Yes No

If Yes, explain: _____

SIGNATURE: _____ DATE: _____

FRI COI OFFICER SIGNATURE: _____ DATE: _____