



FRIENDS RESEARCH INSTITUTE, INC.
INSTITUTIONAL REVIEW BOARD
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Conflict of Interest in Research: Financial Disclosure Form

Name of Investigator or
Research Staff Member:

IRB Study #:

Title of Protocol:

Date of Submission:

Please complete this form for each business entity with which you have a relationship, and return it to the IRB office. To help you understand how to answer these questions, please review the definitions that accompany this form.

<p>1. Do you, or any members of your immediate family, have a significant financial interest in a business entity whose activities relate in any way to this research project?</p> <p><input type="checkbox"/> Yes (If you check Yes, please continue to question #2)</p> <p><input type="checkbox"/> No (If you check No, please sign form and return to the IRB office.)</p>
<p>2. Please provide the following information about the significant financial interest (s) identified above. (Use additional pages if needed.)</p> <p>a. Name of business entity:</p> <p>b. Activities or products of the business:</p> <p>c. Is this business a for-profit entity or a not-for-profit entity?</p> <p>d. Is this business publicly or non-publicly traded?</p> <p>e. Is this business a closely-held private entity?</p>
<p>3. Please describe the nature of your relationship, or your immediate family's relationship, to the business entity identified above (e.g. consulting relationship, employee, executive position, attending, clinical staff member, faculty, Board of Directors or Trustee, IRB member, honoraria, stock ownership, other, etc.). Please provide details about the nature of your activities with the business entity. (Use additional pages if necessary.)</p>

DECLARATION:

I have answered fully and to the best of my ability and will update this form promptly if my circumstances change.

Signature

Date

FRI DEFINITIONS:

Business: any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other legal entity, organized for profit or charitable (non-profit) purposes.

Closely Held Corporation: a corporation, the stock ownership of which is not widely distributed. Rather, a few shareholders are in control of corporate policy and are in a position to benefit personally from the policies.

Conflict of Interest: a situation in which significant financial interests in a business, or other personal considerations provided by a business, may compromise, or have the appearance of compromising, an investigator's (or investigator's staff's) professional judgment in planning, conducting or reporting research, the results of which could affect the aforementioned business, either directly or indirectly.

Immediate Family: the investigator's spouse, minor children, and any other persons living in the same household.

Investigator: the principal investigator and/or any other person, who is responsible for the design, conduct, or reporting of research. The term "investigator" also means the investigator's immediate family.

Research (HHS regulation 45 CFR 46.102(d)): a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Note: The following definitions for "Significant Financial Interest" may be different from State definitions such that it may be a prohibition under state codes of ethics to receive outside interests.

Significant Financial Interest (as defined by DHHS/PHS/NIH):

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - (i) With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - (ii) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution'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 the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

3. The term *significant financial interest* does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
- 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.

Significant Financial Interest (as defined by FDA):

1. Compensation made to the investigator, in which the value of compensation could be affected by study outcome. This requirement applies to all covered studies, whether ongoing or completed, as of February 2, 1999; or
2. A proprietary interest in the tested product, including, but not limited to, a patent, trademark, copyright or licensing agreement. This requirement applies to all covered studies, whether ongoing or completed as of February 2, 1999; or
3. Any equity interest in the sponsor of a covered study (i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices). This requirement applies to all covered studies, whether ongoing or completed; or
4. Any equity interest in a publicly held company that exceeds \$50,000 USD in value. These must be disclosed only for covered clinical studies that are ongoing on or after February 2, 1999. The requirement applies to interests held during the time the clinical investigator is carrying out the study and for 1 year following completion of the study; and
5. Significant payments of other sorts, which are payments that have a cumulative monetary value of \$25,000 USD or more, made by the sponsor of a covered study to the investigator or the investigators' institution (FRI) to support activities of the investigator exclusive of the costs of conducting the clinical study or other studies (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria) during the time the clinical investigator is carrying out the study and for 1 (one) year following completion of the study. This requirement applies to payments made on or after February 2, 1999.

Significant Financial Interest (as defined by NSF): anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term does not include:

1. Salary, royalties, or other remuneration from the institution; or any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program (SBIR) or Small Business Technology Transfer Program (STTR); or
2. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; or
3. Income from service on advisory committees or review panels for public or nonprofit entities; or
4. Financial interests in business enterprises or entities if the value of such interests does not exceed \$5,000 USD or represent more than a 5% ownership interest for any one enterprise or entity when aggregated for the investigator and the investigator's spouse and dependent children.