



Financial Interest Disclosure Form for Regis College Investigators

All Principal and other Investigators proposing to participate in research must complete this form and first return it to the Chair of the Regis College Institutional Review Board (IRB) or his/her designee prior to or when submitting a funding proposal. Information disclosed in this form is confidential- and will be released only on a need-to-know basis. If there are any responses indicating the presence of a financial interest, the IRB Chairperson or his/her designee must submit this form for review and signature to the Investigator's Department Chairperson/Program Director/Associate Dean. If the Department Chairperson/Program Director/Associate Dean is or will be directly involved in the proposed research, the Dean must sign in the space designated for the Department Chairperson/Program Director/Associate Dean. It is the responsibility of the Investigator to update this information promptly if it should change prior to completion of the proposed research. It is the responsibility of the Principal Investigator (PI) to ensure that each Investigator working under his or her supervision on the proposed research project submits this disclosure form when required by the Regis College Policy on Conflict of Interest in Research. The IRB Chair or his/her designee will inform the Grant Officer that this paperwork has been filed. Pertinent **Definitions** can be found on the last page of the form.

Section 1 – Information and Questions for ALL Projects

Name of Investigator:
Date Financial Conflicts of Interest (FCOI) training was completed: (see attached for training opportunities)
Research Project Proposal Title:
Funding Agency or Organization:
Do you have any Ownership Interest in any entity providing funds for this research? Yourself: <input type="checkbox"/> Yes <input type="checkbox"/> No Your Family: <input type="checkbox"/> Yes <input type="checkbox"/> No
Do you have any direct and/or personal ownership interest in any entity that owns intellectual property that could reasonably appear to be affected by this research project? Yourself: <input type="checkbox"/> Yes <input type="checkbox"/> No Your Family: <input type="checkbox"/> Yes <input type="checkbox"/> No
Do you have any Ownership Interest in any entity that could reasonably appear to be affected by this research project? Yourself: <input type="checkbox"/> Yes <input type="checkbox"/> No Your Family: <input type="checkbox"/> Yes <input type="checkbox"/> No

Do you serve as a paid consultant, officer, administrator, board member, or speaker for any entity that is providing funds for this research project, that could reasonably appear to be affected by this research project, or that has an interest in intellectual property that could reasonably appear to be affected by this research project?

Yourself: Yes No

Your Family: Yes No

Have you received in the last 12 months or will you receive in the next 12 months more than \$5,000 (in cash or of any monetary value) from an entity that could reasonably appear to be affected by this research project (other than your salary from Regis)? To answer this question, you should add the amount you receive to the amount(s) family members receive.

Yourself: Yes No

Your Family: Yes No

Is there anything not covered in the above questions that you believe might constitute a potential conflict of interest or create the appearance of being a conflict of interest related to this research project?

Yourself: Yes No

Your Family: Yes No

If this is a Non-federal Project, PROCEED to Section 3.

For federal projects CONTINUE to Section 2.

Section 2 – Additional Questions Applicable to Federal Projects

Do you (or your family) have a Significant Financial Interest that could reasonably appear to *be related to the your institutional responsibilities* which *when aggregated would exceed the value of \$5,000*:

Yourself: Yes No

Your Family: Yes No

Did you receive *any* reimbursement for travel or sponsored travel related to your institutional responsibilities from an entity *other than* the following:

- 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.

Yes No

Section 3 – Detailed Financial Disclosure

If you answered YES to any question on this form (Section 1 or Section 2), specifically describe the financial interest or affiliation and its relationship to this research project or, in the case of a federal project, its relationship to your institutional responsibilities, in the space provided here. If the interest consists of money or something else of value that you or your family members have received or will receive, you must disclose the amount of money or value. If the interest consists of equity that you own or will own, you must provide the current value (if any) of the equity and the percentage of ownership of the company that it represents. **You may use the space below or attach an additional sheet if needed.**

- Name of the entity in which you or your family has or will receive a financial or other interests:

- Dollar amount or value of your financial interest and/or description of equity interest, including percent interest in entity:

- Relationship to the entity:

Travel Disclosure:

- Dollar amount or value if known: _____
- Purpose of trip: _____
- Sponsor Name: _____
- Destination: _____
- Duration: _____

Investigator Certification

By signing below, the Investigator hereby certifies that all of the information contained on this form is true and correct to the best of his or her knowledge and that he or she has made reasonable efforts to assure that accurate and complete information has been provided.

By signing below, the Investigator acknowledges that they are subject to, among other things, Regis College's Conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, the Conflict of Interest in Research Policy and of 42 CFR 50, subpart F, Promoting Objectivity in Research.

Signature of Investigator

Date

Signature of IRB Chairperson or his/her Designee

Date

Section 4 – Administrator Certification

By signing below, the Department Chairperson hereby certifies that he or she has reviewed this form and has determined that (please check one)

- A Significant Financial Interest (SFI) was disclosed and will I defer to the full Institutional Review Board to determine whether the SFI is a financial conflict of interest and if it is related to this research project.
- A conflict of interest exists and the department cannot recommend approval of this research project.
- A conflict of interest exists but it is minimal (less than \$5,000 per year) and the department does NOT recommend management, reduction or oversight of the research project.
- A conflict of interest exists but it can be reduced, eliminated or managed as described in the space below or attach a separate sheet of paper if necessary:

Department Chairperson's/Program Director's/Associate Dean's Signature*

Date

* If directly involved in the research project, the Dean must review and sign

* Dept. Chair's/Program Director's/Associate Dean's signature is only required when there is an affirmative response, that is, a SFI is disclosed.

Definitions

Family is defined as spouse/domestic partner and dependent children.

Federally Funded means any funding, i.e. grant, cooperative grant, and contract, received from any United States government agency, department or entity.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of Regis College. That is, all activities that derive or descend from the Investigator's standing or expertise and are tied to those responsibilities and activities the Investigator was hired by Regis to perform and for which the Investigator is paid by Regis College. Some examples are, research, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Faculty Governance Committees.

Investigator means any person, regardless of title or position, who participates in the design, conduct, or reporting of funded research or proposed for such funding, which may include, for example, collaborators or consultants.

Principal Investigator of Project Director means any person, regardless of title or position, who is responsible for and has supervision of the design, conduct, or reporting of funded research, or proposed for such funding.

Significant financial interest means:

A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- 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;
- 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
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- Investigators also **must disclose** the occurrence of **any reimbursed or sponsored travel related to their institutional responsibilities**? For example, costs that were paid on your behalf and not reimbursed to you so that the exact monetary value may not be readily available provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by:
 - 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 details of this disclosure will include, at a minimum,
 - the dollar amount or value
 - the purpose of the trip,
 - the identity of the sponsor/organizer,
 - the destination, and
 - the duration.
- Ownership Interest means equity interests including stocks and stock interests
- Training Opportunities for Financial Conflict of Interest: an online tutorial may be found here: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> and the certificate of completion attached to this document