

EMORY UNIVERSITY
EXTERNAL INVESTIGATOR REPORT OF FINANCIAL INTERESTS IN RESEARCH
(US Public Health Services [PHS] STUDIES ONLY)

INSTRUCTIONS FOR COMPLETING THIS FORM:

WHO MUST COMPLETE THIS FORM?

At a minimum, an *External Investigator Report of Financial Interests in Research* must be provided for **External Investigators** who meet the following criteria:

- Project Directors, Principal Investigators, and/or members of the research team identified as Senior or Key Personnel on the grant or contract application, progress report, or any other report;
- Individuals identified by the Principal Investigator or Project Director who are responsible for and have substantial independent decision making in respect to the design, conduct or reporting of the research, such as Collaborators or Consultants named on the grant; and
- The **External Investigator** must report Significant Financial Interests for himself /herself and for his/her spouse, same sex domestic partner and dependent children that are related to the Investigator's institutional responsibilities.

WHY MUST THIS FORM BE COMPLETED?

In situations where Emory is the primary awardee of a PHS funded grant, Emory is responsible for monitoring and, if a financial conflict of interest is found, reporting the significant financial interests of ALL Investigators named on the grant, including subrecipients, external consultants/collaborators who are listed as Senior or Key Personnel, etc. If the subawardee institution indicates on the consortium letter that they do not have a policy that is in compliance with the 2011 revised federal regulation on Financial Conflict of Interest at 42 CFR Part 50 Subpart F, then the Investigators named on the subaward must complete this form.

WHEN TO DISCLOSE?

- BEFORE the proposal is submitted;
- At the time of the Annual Progress Report; and
- Within 30 days of learning of a new financial interest related to the grant

The original *External Investigator Report of Financial Interests in Research* form must be submitted with the proposal to the Office of Sponsored Programs. One copy should be retained with the principal investigator's records relating to the project.

WHERE DOES THIS FORM GO?

You will submit this form to the Research Administrator of Emory's PI. S/he will submit the form to the Office of Sponsored Programs (OSP) through the Emory Proposal Express System. Upon review of this form, if the OSP Analyst finds that **ANY** of the Significant Financial Interests are checked, this form will be forwarded to the COI Review Office at the following email address: COI-Office@listserv.cc.emory.edu

A member of the COI Review Office might contact you for additional information.

EXTERNAL INVESTIGATOR REPORT OF FINANCIAL INTERESTS IN RESEARCH

Grant Title: _____

Subrecipient Organization: _____

Grant/Proposal Number (if available): _____

Emory PI/PD Name: _____

Section I: Personal Information

External Investigator Name: _____

Phone Number: _____

Email: _____

Your role in the study:

- Study Site Principal Investigator
- Other (specify): _____

Section II: Significant Interest Disclosure

Check all financial interests related to your institutional responsibilities (i.e., teaching, research, clinical or administrative duties) that apply to you (including immediate family, individually or in aggregate).

Check Boxes After Printing – You MUST check at least one.

- Payments of \$5,000 or more including salary, consulting fees, royalty or licensing payments from intellectual property, honoraria and/or gifts received within the past 12 months or anticipated over the next 12 months (excluding salary, grant support, and other payments for services from Emory University or your home institution);
- Equity or ownership interest (includes stock options) valued at \$5,000 or more as determined by reference to its publicly listed price (excluding mutual funds);
- Any equity or ownership interest, if the value cannot be determined by reference to publicly listed prices (privately held companies, for example, start-up companies);
- A position as director, officer, partner, trustee, employee, or any other position of management;
- Payments of \$5,000 or more for patent rights, or royalties from such intellectual property rights, whose value may be affected by the outcome of the research, including royalties under any royalty-sharing agreements involving Emory University or your home institution;
- Any combination of remuneration, fees, royalties, or honoraria, which exceeds \$5,000 when aggregated, received within the past 12 months or anticipated for the next 12 months, from an entity whose products or services are used or studied in the research or who are developing products or services that the research is intended to study or evaluate; or
- Any compensation whose value could be affected by the outcome of the research.
- Any reimbursed or sponsored travel, not including travel that is reimbursed or sponsored by (1) a federal, state, or local government agency; (2) an Institution of higher education; (3) an academic teaching hospital; (4) a medical center; or (5) a research institute affiliated with an Institution of higher education.
- None of the above.

Certification

I certify that:

1. All **Significant Financial Interests** meeting the criteria above have been disclosed.
2. If I am the Principal Investigator, I have obtained and submitted disclosures for all members of the research team meeting the definition of "Investigator" as defined herein.
3. I am aware and understand that I have an ongoing responsibility to update my report immediately upon any change in outside financial activities that are related to this research project. Additionally, if I am Principal Investigator for this research project, I understand that it is my responsibility to ensure that the other members of the research team update their disclosures on an ongoing basis as their circumstances change.
4. I have read and understand Emory University policies regarding conflict of interest disclosure, including the Emory Statement of Guiding Ethical Principles available [here](#) and Policy 7.7 at <http://policies.emory.edu/7.7>.
5. I have completed the NIH Office of Extramural Research Conflict of Interest tutorial available at: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

Investigator Signature*

Date

External Investigator Name: _____

* No "per" signatures or stamps will be accepted

DEFINITIONS YOU NEED TO KNOW TO COMPLETE THIS FORM:

INVESTIGATOR: An **Investigator** is, at minimum, the Project Directors, Principal Investigators, members of the research team identified as senior/key personnel on the grant or contract application, progress report, or any other report. In addition, individuals identified by the Project Director or Principal Investigator who are responsible for and have substantial independent decision making in respect to the design, conduct or reporting of the research, such as Collaborators or Consultants named on the grant.

COMPENSATION: **Compensation** means anything of monetary value including, but not limited to, salary, consulting fees, honoraria, or other payments for services of any type, including speaking, teaching, and educational engagements, as well as gifts to an **Investigator**.

INSTITUTIONAL RESPONSIBILITIES: means those activities related to an Investigator's Research, Teaching, Clinical, Administrative or Professional Duties

SIGNIFICANT FINANCIAL INTEREST: A **Significant Financial Interest** means interests held individually by the Investigator, his/her spouse or same-sex domestic partner, and dependent children that must be added together and the aggregate value used to determine limits set forth below:

- (a) Compensation or honoraria received from entities if valued at more than \$5,000; do not include compensation or honoraria from (1) a federal, state, or local government agency; (2) a US Institution of higher education; (3) a US academic teaching hospital; (4) a US medical center; or (5) a research institute affiliated with a US Institution of higher education.
- (b) IP licensing fees and/or royalties valued at more than \$5,000
- (c) ownership interests in publicly held companies (i.e., stock/options, dividends, equity) that are valued at more than \$5,000
- (d) any ownership interests (i.e., stock/options, dividends, equity) that you hold in privately held entities (i.e., start-up companies, LLC's)
- (e) holding any management position (e.g., director, officer, trustee, management employee) in an entity outside of your home institution.
- (f) Reimbursed or sponsored travel (note that for PHS purposes, this **does not include** travel that is reimbursed or sponsored by (1) a federal, state, or local government agency; (2) a US Institution of higher education; (3) a US academic teaching hospital; (4) a US medical center; or (5) a research institute affiliated with a US Institution of higher education.

The following items are NOT considered to be a Significant Financial Interest:

- (a) Salary or other payments for services from Emory University or your home institution
- (b) Gifts to your home institution provided the Investigator does not have signing authority for the account.
- (c) Income from non-promotional educational seminars, lectures, or teaching engagements sponsored and paid for by governmental entities
- (d) Income from service on advisory committees or review panels established by and paid for by governmental entities