



## Policy 7.7

### Policy for Investigators Holding a Financial Interest in Research

**Responsible Official:** VP for Research Administration

**Administering Division/Department:** Research Compliance

**Effective Date:** August 24, 2012

**Last Revision:** March 30, 2017

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#### Overview

Emory University and its faculty, staff and students are committed to the principle of free, open, and objective inquiry in the conduct of its Research mission. Multifaceted relationships between Emory investigators and Industry exist and often complement Research.

This Policy seeks to foster Research by providing guidelines and mechanisms for managing Investigator's Significant Financial Interests and when necessary resolving conflicts of interest. All members of the Emory community responsible for the design, conduct, or reporting of research are required to follow the procedures described in this policy.

#### Applicability

##### A. General Applicability:

This policy applies to all faculty, staff and students at Emory University. The procedures for PHS Investigators shall apply to PHS funded grants or cooperative agreements with an issue date of the Notice of Award that is subsequent to August 24, 2012 and to solicitations issued and contract awarded subsequent to August 24, 2012. This policy shall not apply to research funded solely by PHS SBIR/STTR Program Phase I awards subsequent to August 24, 2012; however, human subject research funded by PHS SBIR/STTR Programs will be subject to this policy.

##### B. Applicability to Subrecipients:

For Research sponsored by the US Public Health Service that involves subcontractors, subgrantees or subawardees (collectively "Subrecipients") at other Institutions, Emory requires a written agreement from Subrecipients that establishes whether Emory's policy or the Subrecipient's policy shall apply to the Subrecipient's Investigators. In all cases, Emory must report to the PHS funding agency any Subrecipient Financial Conflicts of Interest prior to the execution of the subcontract or within 60 days of identification of a new Financial Conflict of Interest by the Subrecipient or Emory that arises during the term of the subcontract.

1. If the Subrecipient's policy is used, the Subrecipient must certify that its financial conflict of interest policy is compliant with 42 CFR Part 50 and 45 CFR Part 94 and will be responsible for ensuring that the Subrecipient Institution and its Investigators comply with the federal regulations. Subrecipients must report to Emory as the awardee Institution, any identified Financial Conflict of Interest within 10 business days of the management plan agreement with the Subrecipient's Investigator, but no later than 45 days after identification of the Financial

Conflict of Interest by the Subrecipient. The details of the Financial Conflict of Interest will be reported to the funding agency as required under applicable regulations or policies.

2. If Emory's policy is used, the Subrecipient must ensure that its Investigators submit the Investigator Financial Interest Related to Research Form to Emory at the time of application by Emory or at the time the Subrecipient signs an institutional letter of support if during an on-going award grant or contract.

## Policy Details

### **General Requirements:**

Emory University will manage, minimize, or eliminate Significant Financial Interests of Investigators to ensure that research will be free from bias resulting from Investigator financial interests. All Investigators, *(this term includes 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; and/or 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)* are required to report to Emory any financial interests that could affect or be affected by Research on which they are working or proposing to work on at Emory. Emory Investigators who are funded by a 1PHS agency must follow a separate disclosure process for Significant Financial Interest related to their Institutional Responsibilities that is described in A. 3.

Emory will review an Investigator's disclosed Significant Financial Interests and determine an appropriate management plan. In making these determinations, Emory works to achieve the following goals.

- Safeguard the academic integrity of Emory Research and educational programs.
- Ensure that the Research project is objective and without bias in the design, conduct or reporting of the Research.
- Ensure that Research sponsors' access to Emory equipment, supplies and intellectual property rights is appropriate and consistent with applicable law, Emory policy, and Emory's financial and reputational interests.
- Address unique circumstances and conditions that may be presented by individual cases.

#### **A. Reporting Requirements and Process**

##### **1) Overview:**

The definitions in the Policy describe Significant Financial Interests Requiring Disclosure. Individuals may have difficulty deciding if an interest falls within the various categories; therefore, **individuals should contact the COI Review Office for assistance.**

Emory through its Conflict of Interest Review Committee ("the Committee"), or its delegates, will recommend whether the interest must be managed, reduced or eliminated or whether a Financial Conflict of Interest exists. Per federal regulations and this policy, **Investigators cannot make the decision about whether a Significant Financial Interest must be managed or whether it is a Financial Conflict of Interest; this determination is made through the review process.**

##### **PHS Investigators**

Due to changes in the regulations, PHS Investigators must disclose all Significant Financial Interests that are related to their Institutional Responsibilities. The Committee will recommend to the VP of Research Administration which Significant Financial Interests are related to a specific research project, whether a management plan is necessary, and whether the interests are a Financial Conflict of Interest. As required by federal regulations, Emory will report to the funding agency Financial Conflicts of Interest for PHS supported projects and provide information to the public when a written request is received.

##### **2) Institutional Official**

The Institutional Official is the person designated by Emory University to oversee the solicitation and review of financial reporting statements from any Investigators who will be participating in Research. For purposes of this Policy, the Institutional Official is the Vice President for Research Administration or his/her designee(s).

##### **3) Reporting Requirement and Methods for Reports:**

All Investigators are required to report Significant Financial Interests both on an annual basis and within thirty (30) days after a new Significant Financial Interest is received or acquired (e.g. through purchase, marriage, or inheritance). Schools and other administrative units may also require faculty, clinical physicians, and administrative directors to report all external compensated activities. Investigators must comply with requests from the Committee for additional information.

a) **Annual Investigator Certification Reports:**

At least annually, or upon employment at Emory, any Emory Faculty engaged in Research, or who wishes to be eligible to engage in Research, must complete an *Annual Certification Form* through the online eCOI system located at [www.ecoi.emory.edu](http://www.ecoi.emory.edu). Once submitted, this form will be reviewed by the dean or director (or his/her designee) of the unit for which the Investigator works. Deadlines may be adjusted by the Conflict of Interest Review Office with consultation by the Deans. Faculty who are Investigators should include on this form any information required by their school or administrative unit which, at a minimum, must include any Significant Financial Interest Requiring Disclosure Faculty **received** during the last 12 months.

**External Activity Reports:**

Per Policy **12.2.b Policy on Consulting, Teaching, and Other Services Outside the University.**

in the faculty handbook, all Faculty are required to report all external (non-Emory) activities. This includes all outside consulting activities. **The activity must be disclosed prior to engagement in the activity and will be reviewed by the dean or director (or his/her designee) of the unit for which the Faculty works.** This form can be completed through the online eCOI system located at [www.ecoi.emory.edu](http://www.ecoi.emory.edu). When these activities are related to a Faculty's Institutional Responsibilities, they could be considered Significant Financial Interests Requiring Disclosure.

b) **Transactional Reports:**

**Significant Financial Interests Requiring Disclosure** are interests held individually by the Investigator, his/her spouse or same-sex domestic partner, and dependent children must be added together and the aggregate value used to determine limits set forth below:

(a) Remuneration or honoraria received from entities if valued at more than \$5,000

(b) IP licensing fees and/or royalties

(c) ownership interests (i.e., stock/options, dividends, equity) that are valued at more than \$5,000

(d) any ownership interests (i.e., stock/options, dividends, equity) in privately held entities(i.e., start-up companies, LLC's)

(e) holding any management position (e.g., director, officer, trustee, management employee) in a non-Emory entity

**PHS Disclosure Requirements**

PHS Investigators (Faculty and staff) must disclose all Significant Financial Interests related to their teaching, research, administrative, or clinical duties (**Institutional Responsibilities**). Additionally, they must disclose any reimbursed or sponsored travel expenses, which are valued at more than \$5,000 annually from a single entity and which are related to their administrative, clinical, or teaching duties at Emory.

It does not include travel that is reimbursed or sponsored by the following:

- US Federal, state, or local government agency,
- A US Institution of higher education,
- US academic teaching hospital,
- US medical center, or
- a Research institute that is affiliated with a US Institution of a higher education.

Also, travel expenses paid by a third party through a grant to, or a contract with, Emory do not need to be reported.

Each Investigator who holds a **Significant Financial Interest Requiring Disclosure** must report the existence and nature of the interest **prior to** submitting a formal proposal to any proposed sponsor of the Research, or, prior to conducting the Research, if the Research is internally funded. At the time of routing a grant or contract proposal for sponsored Research, Investigators or their designees are responsible for accurately completing a **Proposal Financial Interest in Research Report (PFIRR)**, which details information about the study and lists Emory Investigators on the study. The Investigators will then be prompted to complete an **Investigator Financial Interest in Research Report(IFIRR)**. Emory Investigators must complete these forms through the eCOI Software Program found at [www.ecoi.emory.edu](http://www.ecoi.emory.edu).

**PHS & NSF Review Procedures**

When the Investigator Financial Interest in Research Report is submitted, the Committee will review the forms and recommend to the Institutional Official, or his/her designee, whether any Significant Financial Interests Requiring Disclosure must be managed, reduced, or

eliminated. For PHS funded activities, the Committee will recommend whether any Significant Financial Interest Requiring Disclosure is related to the research project and whether the Significant Financial Interest Requiring Disclosure is a Financial Conflict of Interest that must be reported to the PHS funding agency. For NSF funded activities, the Committee will recommend whether a Financial Conflict of Interest exists.

**c) Change in Status and Updating Reports:**

**Investigators** (faculty and staff) are required to update reports to reflect changes in or additions of Significant Financial Interests Requiring Disclosure. In cases where Investigators are not aware of the existence of a **Significant Financial Interest Requiring Disclosure** at the time of a proposal for Research funding, or if the **Significant Financial Interest Requiring Disclosure** develops after submission of a proposal, Investigators shall report the interest to the Conflict of Interest Review Office through the eCOI system within thirty (30) days of learning of or acquiring the financial interest.

Each year of a research project or study, whether funded or unfunded, an Investigator must update his/her Investigator Financial Interest in Research Report. The form must be updated at the time of the annual progress report, twelve (12) months after the notice of award, or the initiation of research, whichever date is earliest. **This disclosure shall serve as the annual certification for Investigators who do not hold a faculty appointment.**

The Conflict of Interest Review Office shall receive all reports of Significant Financial Interests Requiring Disclosure and the COI Review Committee, or its designees, shall review the disclosed interests as described in Section B. Investigators may use the eCOI Software Program found at [www.ecoi.emory.edu](http://www.ecoi.emory.edu) to update their information.

**B. Conflict of Interest Review Committee**

The Vice President for Research Administration shall appoint a Conflict of Interest Review Committee ("Committee") of not fewer than five, nor more than fifteen voting members.

This Committee shall review and recommend plans for the management, reduction, or elimination of Significant Financial Interests Requiring Disclosure. The Committee is advisory to the Vice President for Research Administration.

It will be the responsibility of this Committee to:

- Review any reports made regarding Significant Financial Interests Requiring Disclosure, whether made on pertinent forms or otherwise brought to the attention of the Committee;
- Request and review any additional materials needed to evaluate the relationship of the interest to the Research;
- Recommend whether the Significant Financial Interest Requiring Disclosure requires a plan to manage, reduce, or eliminate the financial interest and to develop such a plan;
- Recommend, for PHS and NSF funded activities, whether a Significant Financial Interest Requiring Disclosure constitutes a Financial Conflict of Interest;
- Communicate its plan to the Investigator, Dean, and Vice President for Research Administration for approval.

**PHS/NSF Procedures**

For projects funded by PHS, the Committee shall determine whether the Significant Financial Interest Requiring Disclosure is related to a particular research project. They shall also determine whether such interest is a Financial Conflict of Interest pursuant to 42 CFR Part 50/45 CFR Part 94 and to the NSF policy statement.

**C. Plans for Management, Reduction or Elimination of a Significant Financial Interest Requiring Disclosure:**

As appropriate, the Committee develops management plans that focus on the steps by which the objectivity of the Research can be ensured. Components of such a plan may include, but are not limited to:

- Public disclosure of an Investigator's Significant Financial Interest;
- For research involving human subjects, disclosure of Investigator financial interests directly to participants;
- Appointment of an independent reviewer of data, manuscripts, and/or presentations;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from an Investigator's financial interest;
- Modification of any Research proposal or plan;

- Change in personnel or personnel responsibilities, or disqualification of an Investigator from participating in all or a portion of any Research;
- Reduction or elimination by an Investigator of a financial interest; and/or
- Severance of any relationships that created the financial interest.

### **1) Notification of Committee's Decision and Recommended Approval of Plan:**

When the Committee advises that an Investigator's Significant Financial Interest Requiring Disclosure must be managed, reduced, or eliminated, the Committee will inform the Vice President for Research Administration and the Investigator's Dean of this recommendation and the management plan. For PHS and NSF funded activities, the Committee also shall notify the Vice President for Research Administration and Dean of the Committee's recommendation that a Financial Conflict of Interest exists. The Vice President for Research Administration and/or Dean shall notify the Conflict of Interest Review Committee within seven (7) days if he/she/they object to the proposed plan. If neither the Vice President for Research Administration nor the Dean provides notification of an objection to the proposed plan within (7) days of receipt, the determination of the Committee and any resulting plan will become final. The Conflict of Interest Review Office will then notify the Investigator of the plan. If either the Vice President for Research Administration or the Dean does object, Committee representatives shall discuss the matter with the Vice President for Research Administration and the Dean and attempt to develop a mutually agreeable plan. If agreement on a plan cannot be reached within fourteen (14) days after receipt of an objection from the Dean or Vice President for Research Administration, then the recommendations of all parties shall be presented for a final decision to the Executive Vice President for Academic Affairs or Executive Vice President for Health Affairs, which decision shall be provided within 10 days of receipt of the recommendations.

### **2) Investigator Notification and Appeals:**

Investigators shall be notified by the COI Review Office when a Significant Financial Interest Requiring Disclosure must be managed and when a Financial Conflict of Interest exists. The final recommended plan for the management, reduction, or elimination of the Significant Financial Interest Requiring Disclosure or Financial Conflict of Interest will be sent to the Investigator at the same time. If he/she wishes to appeal the plan, an appeal may be made to the Conflict of Interest Review Committee within 10 days of receipt of the notification. Should the Investigator not file a written appeal with the Committee by such time, then the Investigator shall be considered to have waived his/her right to appeal that and determination of the Committee shall be final. If the Investigator's appeal is denied by the Committee, then he/she may make a subsequent appeal to the Executive Vice President for Academic Affairs or Executive Vice President for Health Affairs, as appropriate. The appropriate Executive Vice President shall notify the Investigator within 10 days as to whether the appeal is granted or denied. During the pendency of any appeal to the Committee or appropriate Executive Vice President, the Investigator must either (a) agree to abide by the initial recommendations of the Committee; or (b) remove himself/herself from the Research; or (c) not expend any funds under any award from a sponsor for the conduct of the Research at issue.

### **3) Research with Human Subjects**

Special precautions must be taken to avoid bias with respect to Research involving Human Subjects involving the evaluation of strategies or products that may affect or be affected by the financial interests of Emory or Emory Investigators. An Emory Investigator shall not ordinarily participate in any Research involving human subjects that encompasses evaluation of such a strategy or product if he/she has a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of the Research unless he/she presents a compelling justification for a waiver of this policy based on his/her unique qualifications as an Investigator. The degree of risk to human subjects and the compelling justification will be reviewed by the Committee. If compelling circumstances justify a waiver of this policy, the Research will be subject to stringent management measures to ensure the safety of the human participants and the integrity of the Research. The IRB must review and approve any management plan for human subject Research. The IRB may require additional safeguards to protect human subject participants.

In accordance with 42 CFR Section 50.606(c), in any case in which the Department of Health and Human Services determines that a Public Health Service-funded project of clinical Research, 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 with a conflicting interest that was not reported or managed as required by this Policy or the applicable regulations, then Emory shall, at minimum, require the Investigator involved to disclose the conflicting interest in each public presentation of the results of the Research and to request an addendum to previously published presentations. An Investigator who has failed to report a Significant Financial Interest related to clinical Research will be subject to sanctions described in Section E. If the project is funded by a PHS agency, the Investigator may also be subject to the Retrospective Review and Mitigation Plan procedures described in Section E.

#### **D. Reporting and Expenditure of Funds**

No expenditure of sponsor funding for Research shall occur with respect to any Research project for which the Committee has determined that a management plan is required unless and until all reporting requirements have been met. For any Significant Financial Interest Requiring Disclosure that is identified after the funding for the Research is awarded, Emory will determine whether a management plan is required and for PHS awards, whether a Financial Conflict of Interest exists. As required by the sponsor's regulations or policies, Emory shall report to the funding agency any management plans or Financial Conflict of Interest within 60 days of the interest's identification. The outcome of Committee reviews will be communicated to the Institutional Review Board (IRB) for all Research involving human subjects and to the Institutional Animal Care and Use Committee (IACUC) for all Research involving animal subjects. The IRB may require additional measures to protect the safety and welfare of Research subjects under their purview.

The procedures and requirements for PHS Awards are noted below:

##### **PHS Awards**

###### **A. Reports to Funding Agency**

As required by federal regulations, Emory shall report the following information regarding Financial Conflicts of Interest to the funding agency through the eRA Commons:

- i. Project Number
- ii. PD/PI or Contact PD/PI if multiple PD/PI model is used;
- iii. Name of the Investigator with the financial conflict of interest;
- iv. Name of the entity with which the Investigator has a financial conflict of interest;
- v. Nature of the financial interest (e.g. equity, consulting fee, travel reimbursement, honorarium);
- vi. Value of the financial interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value;
- vii. A description of how the financial interest relates to the PHS-funded research and the basis for Emory's determination that the financial interest conflicts with such research; and
- viii. A description of key elements of the Institution's management plan including:
  - a. Role and principal duties of the conflicted Investigator in the research project;
  - b. Conditions of the management plan;
  - c. How the management plan is designed to safeguard objectivity in the research project;
  - d. Confirmation of the Investigator's agreement to the management plan
  - e. How the management plan will be monitored to ensure Investigator compliance;
  - f. Other information as needed or requested by the funding agency.

Additionally, each award year Emory must provide the funding agency an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the project period (including extensions with or without funding). The annual FCOI Report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. Emory must report to the agency the annual FCOI report at the time of the progress report.

###### **B. Reports to Public**

As required by federal regulations and upon written request, Emory shall provide to any requestor written information about Financial Conflicts of Interest, which were determined to be a Financial Conflict of Interest after August 24, 2012, of an individual who is listed as a Senior or Key Personnel on a US Public Health Service (PHS) award. Requests must be in writing and received through the US mail. The request must identify the specific PHS project number and the name of Investigator for whom information is being requested. The request must include a named recipient and return address with a physical street address, P.O. Boxes are not acceptable. Emory will note in its written response that the information is current as of the date of the correspondence, and is subject to updates at least annually and within 60 days of Emory's identification of a new conflict of interest, which must be requested under separate cover by the requestor. The following information will be provided to the requestor:

- i. Project Number
- ii. Name of the Investigator with a conflicted interest;
- iii. Investigator's title and role with respect to the research project;
- iv. Nature of the financial interest (e.g. equity, consulting fee, travel reimbursement, honorarium); and
- v. Value of the financial interest (in ranges), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable

measure of fair market value.

#### **E. Compliance with this Policy and Relevant Law**

The Investigator is ultimately responsible for ensuring that he/she makes any necessary disclosures to Emory required by this Policy and follow any prescribed plan for the management, reduction, or elimination of an identified Significant Financial Interest Requiring Disclosure. Failure to do so shall be deemed a violation of this University Policy. The Investigator's department, Dean and/or the Conflict of Interest Review Office may inspect any necessary records to ensure compliance with the plan.

The Conflict of Interest Review Office and/or the Conflict of Interest Review Committee, in consultation with the Vice President for Research Administration and the Dean, shall be responsible for investigating and resolving any alleged violations of this Policy and may recommend appropriate actions to the Dean and/or the Vice President for Research Administration to enforce this Policy and/or to impose a sanction for non-compliance. The Dean and/or the Vice President for Research Administration shall review and take appropriate action to implement such recommendations as he/she/they deem appropriate in the circumstances. Sanctions for non-compliance may include reprimands or other appropriate measures, up to and including termination. In investigating any violation of this Policy, the Conflict of Interest Review Office, and/or the Conflict of Interest Review Committee shall determine if any violation of this Policy has biased the design, conduct or reporting of the Research sponsor, or on its own initiative shall take appropriate corrective action, which may include, but is not limited to, taking appropriate steps to maintain the objectivity of the Research. The Conflict of Interest Review Office and/or the Conflict of Interest Review Committee shall promptly notify the Dean and the Vice President of Research Administration of any conflicts not resolved to the satisfaction of the Committee, along with recommended actions. The Conflict of Interest Review Office shall promptly notify the Research sponsor and affected Emory units of any violations and/or corrective actions, as described above.

Emory Investigators involved in Research or technology transfer are expected to comply with all applicable regulations and laws pertaining to the conduct of Research and the sale and purchase of securities.

##### **1. Required PHS Procedures for failure to comply with policy or management plan**

In addition the above review and sanctions, Emory and PHS Investigators are subject to the following procedures when financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by Emory to constitute a financial conflict of interest; failure by the Emory to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan.

A. Emory must implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;

B. Within 120 days of Emory's determination of noncompliance, Emory must complete a retrospective review of the Investigator's activities and the PHS funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

C. Emory must document the retrospective review and include, at minimum, the following information:

- (1) Project number;
- (2) Project title;
- (3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
- (4) Name of the Investigator with the FCOI;
- (5) Name of the entity with which the Investigator has a financial conflict of interest;
- (6) Reason(s) for the retrospective review;
- (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- (8) Findings of the review; and
- (9) Conclusions of the review.

D. Based on the results of the retrospective review, if appropriate, Emory shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. The Conflict of Interest Review Office shall contact the Office of Research Compliance and alert them of the findings of the retrospective review.

If the retrospective review team members find bias, Emory is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and Emory's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, Emory will submit to the PHS Awarding Component FCOI reports annually, as specified elsewhere in

this subpart. Depending on the nature of the financial conflict of interest, Emory may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of Emory's retrospective review.

#### **F. Maintenance of Records**

The Conflict of Interest Review Office shall be responsible for maintaining records, identifiable to each project, all transactional reports of Significant Financial Interests, and all actions taken by the Conflict of Interest Review Committee or other appropriate units within Emory to manage any actual or potential Financial Conflicts of Interest for the longer of at least three (3) years from: (a) the date of submission of the final expenditures report, for federally funded grants; (b) from the date of termination or completion of the award; or (c) from the date of the resolution of any action by any governmental agency involving the records; or (d) as applicable, from any other date specified in 45 CFR Section 74.53(b) for different situations, as appropriate.

#### **G. Certification**

The Office of Sponsored Research Projects shall certify those elements enumerated in Title 42, Section 50.604(g) of the Code of Federal Regulations for all Public Health Service applications for Research funding.

#### **H. Training**

Each Investigator must complete training prior to engaging Research and at least every four years, and immediately under the designated circumstances:

1. When Emory's policy change in a manner that affects Investigator requirements;
2. When an Investigator arrives to Emory;
3. When an Investigator is not in compliance with this policy or management plan.

### **Definitions**

The following terms as used in this Policy shall have the following meanings:

**Compensation** shall mean anything of monetary value including, but 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 Investigators.

**Equity Interest** shall mean stocks, stock options, or other ownership interests.

**Financial Conflict of Interest** means any Significant Financial Interest Requiring Disclosure that is determined by Emory University to significantly and directly affect the design, conduct or reporting of Research.

**Institutional Official** means the person appointed by Emory University, or his/her designee(s), to solicit and review statements from Investigators of Significant Financial Interests Requiring Disclosure. [See Section 42 CFR 50.604(b) and 45 CFR Section 94.4(b)]. Emory University has appointed the Vice President for Research Administration as its Institutional Official.

**Investigator** shall mean 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 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. In general, other significant contributors used on a grant application or report are not considered investigators unless the PI has indicated that the individual is responsible for and has authority to make independent decisions regarding design, conduct, or reporting of the research.

**Institutional Responsibilities** shall mean those activities related to their Research, Teaching, Clinical, Administrative, or Professional Duties at Emory.

**Research** means any systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge, including behavioral and social-sciences research. The term encompasses basic and applied Research as



well as product testing and development. The term includes, but is not limited to, any activity for which Research funding is available from a Public Health Service component that awards funds under grants, cooperative agreements or otherwise. For PHS-funded activities, this term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project or research resources award.

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

- (a) Remuneration or honoraria received from entities if valued at more than \$5,000
- (b) IP licensing fees and/or royalties
- (c) ownership interests (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 a non-Emory entity.

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

- (a) Salary or other payments for services from Emory University
- (b) Gifts to Emory University provided the Investigator does not have signing authority for the Emory 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.

**Significant Financial Interest Requiring Disclosure** means, for Non-PHS projects, an Investigator's Significant Financial Interest (a) that would reasonably appear to be affected by the Research on which the Investigator is working; or (b) that is held in an entity whose financial interests would reasonably appear to be affected by the Investigator's Research. Any Significant Financial Interest Requiring Disclosure must be reported to the Institutional Office or his/her designee.

PHS Investigators must disclose all Significant Financial Interests related to their Institutional Responsibilities – teaching, research, clinical or administrative duties. Additionally, they must disclose any reimbursed or sponsored travel (i.e., the travel was paid for on their behalf, but not reimbursed to them by Emory), related to their administrative, clinical, or teaching duties at Emory. It does not include travel that is reimbursed or sponsored by the following:

- Federal, state, or local government agency,
- an Institution of higher education,
- academic teaching hospital,
- medical center, or
- research institute that is affiliated with an Institution of a higher education.

## Related Links

- Current Version of This Policy: <http://policies.emory.edu/7.7>
- [Statement of Guiding Ethical Principles](http://www.emory.edu/president/governance/ethical_principles.html) (http://www.emory.edu/president/governance/ethical\_principles.html)
- [Emory Bylaws Article IX Conflicting Transactions](http://www.emory.edu/secretary/governance/bylaws.html) (http://www.emory.edu/secretary/governance/bylaws.html )
- [Guidelines for Responsible Conduct of Scholarship and Research](http://www.policies.emory.edu/7.9) (http://www.policies.emory.edu/7.9)
- [Policy on Research Misconduct](http://www.policies.emory.edu/7.8) (http://www.policies.emory.edu/7.8 )
- [Emory IRB Relationships with Other Regulatory Committees p.42, IRB Policies and Procedures](http://www.irb.emory.edu/researchers/formstools/docs/other/PoliciesAndProcedures.pdf) (http://www.irb.emory.edu/researchers/formstools/docs/other/PoliciesAndProcedures.pdf )
- [Conflicts of Interest-Investigators - p.134, IRB Policies and Procedures](http://www.irb.emory.edu/researchers/formstools/docs/other/PoliciesAndProcedures.pdf) (http://www.irb.emory.edu/researchers/formstools/docs/other/PoliciesAndProcedures.pdf)
- [42 CFR 50.601-607](http://www.access.gpo.gov/nara/cfr/waisidx_08/42cfr50_08.html) (http://www.access.gpo.gov/nara/cfr/waisidx\_08/42cfr50\_08.html)
- [45 CFR Part 94](http://www.access.gpo.gov/nara/cfr/waisidx_08/45cfr94_08.html) (http://www.access.gpo.gov/nara/cfr/waisidx\_08/45cfr94\_08.html)
- [National Science Foundation \(NSF\) Regulations at Federal Register, Volume 60, No. 32, July 11, 1995, pages 35822-35823](http://www.access.gpo.gov/cgi-bin/TEXTgate.cgi?WAISdocID=703027174324+2+1+0&WAIAction=retrieve) (http://www.access.gpo.gov/cgi-bin/TEXTgate.cgi?WAISdocID=703027174324+2+1+0&WAIAction=retrieve)
- [National Science Foundation, Award and Administration Guide, Chapter IV, Grantee Standards](http://www.nsf.gov/pubs/policydocs/pappguide/nsf09_1/aag_4.jsp#IVA) (http://www.nsf.gov/pubs/policydocs/pappguide/nsf09\_1/aag\_4.jsp#IVA)

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- Version Published on: Oct 06, 2016
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- Version Published on: Jan 14, 2013 (*Update "PHS Disclosure Requirements" section.*)
- Version Published on: Aug 22, 2012 (*Entire policy updated to reflect changes in federal regulations.*)
- Version Published on: Jun 03, 2009
- Version Published on: Jun 03, 2009 (*Update to reflect current University program.*)
- Version Published on: Mar 30, 2007 (*Original Publication*)

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