Policy 7.7
Policy for Investigators Holding a Financial Interest in Research

This policy version was not current at the time of printing. Please see http://policies.emory.edu/7.7 for the current version.

Responsible Official: VP for Research Administration
Administering Division/Department: Research Compliance
Effective Date: June 01, 2009
Last Revision: June 03, 2009

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 teaching, Research, and service missions. Emory is also committed to transferring knowledge gained and technologies developed through the Research efforts of its faculty, staff, and students for the betterment of society. Multifaceted relationships between Research sponsors or licensees catalyze Research and technology transfer activities. However, on occasion, such relationships may present Emory investigators and administrators with issues regarding perceived or actual conflicts of interest.

This Policy seeks to foster Research and technology transfer by providing guidelines and mechanisms for resolving perceived or actual conflicts of interest and safeguarding Emory's and Emory investigators' reputations for academic integrity. All members of the Emory community responsible for any role in the design, conduct, or reporting of research are required to follow the procedures described in this policy.

This Policy and its procedures comply with federal regulations pertaining to sponsored Research, including the Public Health Service (PHS) Regulations at 42 CFR Part 50, Subpart F, Section 50.601 through Section 50.607 and 45 CFR Part 94, Section 94.1 through 94.6; the National Science Foundation (NSF) Regulations at Federal Register, Volume 60, No. 32, July 11, 1995, pages 35822-35823; and the FDA Regulations at 21 CFR Part 54 regarding the disclosure of reportable financial interests. In the event that at any time this Policy and its procedures are in conflict
with the foregoing regulations, the applicable regulations shall control, and this Policy shall be conformed to comply therewith.

Applicability

A. General Applicability:

This document applies to all faculty, staff and students at Emory University.

B. Applicability to Subrecipients:

For Research that involves subcontractors, subgrantees or subawardees (collectively “Subrecipients”) at other institutions, Emory requires written assurance from Subrecipients that they and the individual Investigators who work for them have a conflict of interest policy that conforms to the requirements of all applicable regulations, including, but not limited to those set forth at 45 CFR Part 94 and 42 CFR Part 50, Subpart F. If any Subrecipient does not have such a conflict of interest policy, then Emory shall require that said Subrecipient adopt and implement such a policy prior to the initiation of any work, and Subrecipient’s failure to promptly do so upon request from Emory shall be considered to be grounds for immediate termination by Emory of any applicable subcontract or subaward. Any assurance required by Emory shall contain the provision that Subrecipients will report to Emory as the awardee Institution, any identified Financial Conflict of Interest. Emory will require a specific assurance from the other institution that any such Financial Conflict of Interest has been reduced, managed, or eliminated. Emory, in turn, will report the Financial Conflict of Interest to any sponsor as required under applicable regulations or policies.

Policy Details

General Requirements:

All Investigators are required to report to Emory Significant Financial Interests that affect, or may be affected by, Research on which they are working, including reporting to Emory any known Significant Financial Interests in entities whose financial interests would reasonably appear to affect the Research. If an Investigator holds a Significant Financial Interest that may reasonably appear to affect, or be affected by, a Research project on which the Investigator is working, then Emory must review the matter and determine if the interest is a Financial Conflict of Interest that should be managed, reduced or eliminated. 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 graduate students, postdoctoral researchers and other Emory personnel are assigned appropriate duties consistent with their status or position.
- 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 this Policy describe Significant Financial Interests and Significant Financial Interests Requiring Disclosure. Individuals may have difficulty deciding if an interest falls within these categories. **Accordingly, individuals should always err on the side of reporting any Significant Financial Interest that they think may affect, or be affected by, Research on which they are working.**

Once any Significant Financial Interest is reported, Emory will (a) confirm that the Significant Financial Interest is a Significant Financial Interest Requiring Disclosure; and if so, (b) determine whether the interest constitutes a Financial Conflict of Interest that must be managed, reduced or eliminated. **Individuals should not make the decision about whether a Significant Financial Interest Related to Research is a Financial Conflict of Interest; this determination is made through the review process.**

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 to Emory Significant Financial Interests that affect, or may be affected by, Research on which they are working, including any known Significant Financial Interests in entities whose financial interests would reasonably appear to affect the Research. Investigators should use the reporting methods below:

a) Annual Investigator Certification Reports:

All Investigators are required to report Significant Financial Interests Related to Research BOTH on an annual basis, and at any time that a new Significant Financial Interest Related to Research occurs. Schools and other administrative units may also require all faculty and administrative directors to report, both annually and transactionally, all external (non-Emory) compensated activities.

By May of each calendar year, or upon employment at Emory, any Emory Investigator engaged in Research, or who wishes to be eligible to engage in Research, must complete an Annual Certification of External Activities and Significant Financial Interests Related to Research Form and file this form with ORA and the dean or director (or his/her designee) of the unit for which the Investigator works. Deadlines may be adjusted by ORA with consultation by the Deans. 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, and should report any Compensation in excess of the reporting thresholds that the Investigator receives OR expects to receive over the upcoming calendar year. The Annual Certification of External Activities and Significant Financial Interests Related to Research Form may be obtained through the web at the following links or by contacting the University Conflict of Interest Office at coi-web@emory.edu:

**School of Medicine:** After July 1, 2009: Click the eCOI link at www.coi.emory.edu

**Rollins School of Public Health:** http://www.sph.emory.edu/AF/conflictDisclosure.php

**School of Nursing:**
http://www.nursing.emory.edu/pulse/departments/administration/documents/coi_son_form.pdf

**Emory College:**
http://www.college.emory.edu/about/planning/grants/pdf/coic_form.pdf
b) **Transactional Reports:**

Each Investigator who holds a Significant Financial Interest Related to Research 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 are responsible for accurately completing an *Emory University Investigator Report of Financial Interests in Research Form*. Completed forms for each Emory Investigator must be submitted with the *Sponsored Programs Administrative Form (SPAF)*, and the conflict of interest certification block must be completed correctly and signed. After June 15, 2009, Investigators may complete these forms through the eCOI Software Program found at www.coi.emory.edu.

If any member of the Emory Community intends to conduct Research using Emory resources (i.e. internally or externally funded Research) in an area in which he/she holds a Significant Financial Interest Related to Research, a *Report to the Emory Conflict of Interest Committee Form* (available by contacting the University Conflict of Interest Office at coi-web@emory.edu) must be submitted to the Office of Research Administration (ORA), and *any perceived or actual conflicts of interest MUST BE managed, reduced or eliminated prior to initiating the Research*.

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

Investigators are required to update reports in real time to reflect changes in or additions of Significant financial Interests Related to Research. In cases where Investigators are not aware of the existence of a Significant Financial Interest Related to Research at the time of a proposal for Research funding, or if the Significant Financial Interest develops after submission of a proposal, then Investigators shall report the interest to ORA within three (3) business days of learning of the interest, using the *Report to the Emory Conflict of Interest Committee Form*. The conflict of Interest committee shall review the interest as described in Section IV.B. After June 15, 2009, Investigators may use the eCOI Software Program to update their information.

d) **Report of Financial Relationships with Potential Licensees:**

Each Emory Investigator shall provide a written report of any relationship with a prospective licensee to his/her Dean, ORA, and Emory's Director of the Office of Technology Transfer (OTT), before Emory or the Investigator commences license negotiations with such party. The Investigator must notify his/her Dean, ORA, and the Emory Director of OTT of any relationship with a prospective licensee that arises during the course of license negotiations, or after execution of the license agreement.

e) **Review of Transactional Reports:**

Upon receipt of a proposal for external funding of Research, the Office of Sponsored Programs (OSP) will review the proposal routing documents, including financial reporting forms, and if Significant Financial Interest Related to Research is noted, forward the information to ORA.

**B. Conflict of Interest Committee**

1) **Committee Composition and Responsibilities:**

The Executive Vice President for Academic Affairs, in consultation with the Executive Vice President for Health Sciences and the Executive Vice President for Finance and Administration, shall appoint a Conflict of Interest Committee (“Committee”) of not fewer than five, nor more than fifteen voting members. At least one voting member shall be unaffiliated with Emory University in that he/she shall not be an employee, agent or contractor of Emory, or a spouse/domestic partner, or child of such a person. ORA shall provide staff support to the Committee. This Committee shall review and recommend plans for the management, reduction or elimination of the interest. 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 Related to Research, 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 Related to Research constitutes a Financial Conflict of Interest;
- Develop a plan to manage, reduce or eliminate any Financial Conflict of Interest;
- Communicate its plan to the Investigator, Dean, and Vice President for Research Administration for approval.

2) Plans for Management, Reduction or Elimination of a Financial Conflict of Interest:

Plans shall focus on developing 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 any Investigator’s interest in a Research sponsor or in an entity whose service or product is the subject of any Research results being reported or in the competitor of such entity; or
- Monitoring of any Research project by independent reviewers; or
- Modification of any Research proposal or plan; or
- Disqualification of any Investigator from participating in all or a portion of any Research; or
- Divestiture by an Investigator of any financial interest in any Research sponsor or entity whose products or services are the subject of the Research or the competitor of such entity.
- Severance of any relationship between an Investigator and a Research sponsor or entity (or competitor thereof) whose service or product is the subject of the Research that may create actual or potential conflicts of interest.

As determined by the Conflict of Interest Committee and the Vice President for Research Administration, in consultation with the Dean, Emory Investigators may, under appropriately managed circumstances, be able to maintain one or more of the following relationships with Research sponsors or licensees of Emory technology: (I) equity participation;(II) service on a governing board or as an officer; (III) service on a scientific advisory board; and (IV) principal investigator for sponsored Research. Emory investigators may also share in "Net Revenues" received from licensees in accordance with Emory’s Intellectual Property Policy.

3) Notification of Committee’s Decision and Recommended Approval of Plan:

When the Committee advises that an Investigator has a Financial Conflict of Interest, the Committee will inform the Vice President for Research Administration and the Investigator’s Dean of this recommendation. The Committee also shall notify the Vice President for Research Administration and Dean of the Committee’s recommended plan for managing, reducing, or eliminating the Financial Conflict of Interest. The Vice President for Research Administration and/or Dean shall notify the Conflict of Interest 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 seven (7) days of receipt, the determination of the existence of a Financial Conflict of Interest and the plan will become final and ORA will 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.

(4) Investigator Notification and Appeals:

Investigators shall be notified by the ORA of the existence of a Financial Conflict of Interest and the final recommended plan for the management, reduction or elimination of the Financial Conflict of Interest. If he/she wishes to appeal the plan, an appeal may be made to the Conflict of Interest 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.

C. Research with Human Subjects

Special precautions must be taken to avoid perceived or actual bias with respect to Research involving Human Subjects that encompasses 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 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. An Investigator who has failed to report a Significant Financial Interest related to clinical Research will be subject to sanctions 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 a Financial Conflict of Interest exists unless and until the Financial Conflict of Interest is reported to the sponsor, and has been managed, reduced or eliminated pursuant to a plan also reported to the sponsor. For any Financial Conflict of Interest that is identified after the funding for the Research is awarded, Emory will report to the sponsor, as required by the sponsor’s regulations
or policies, the Financial Conflict of Interest and the plan for its management, reduction or elimination within 60 days of the interest's identification.

E. Compliance with this Policy and Relevant Law

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

The ORA and/or the Conflict of Interest Committee, in consultation with 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, ORA, and/or the Conflict of Interest Committee shall determine if any violation of this Policy has biased the design, conduct or reporting of the Research, and if so, shall promptly notify the Research sponsor of its determination. Emory, as directed by 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. ORA and/or the Conflict of Interest 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. ORA 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.

F. Reporting Conflicts of Interest; Maintenance of Records

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 and IACUC may require additional measures to protect the safety and welfare of Research subjects under their purview.

For Research involving external sponsorship, ORA will inform OSP of actions taken by the Committee. ORA will notify those sponsors that require notification of the disclosure and action, in accordance with the sponsor’s applicable regulations or policies. Any perceived or actual conflicts of interest must be managed in accordance with this policy, or the sponsor’s requirements, whichever is more stringent. (See Reporting and Expenditure of Funds above.)

ORA 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 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

ORA shall certify those elements enumerated in Title 42, Section 50.604 (g) of the Code of Federal
Definitions

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

**Compensation** shall mean 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 Investigators.

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

**Financial Conflict of Interest** means any Significant Financial Interest Related to Research that is determined by Emory University to constitute a real or perceived conflict of interest affecting Research, or affected by Research, that requires management, reduction or elimination.

**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 the principal investigator and any other person (including but not limited to any collaborator, co-investigator, staff member, student and visiting professor) who is responsible for the design, conduct or reporting of the Research project or proposed Research project. For purposes of this Policy, Investigator shall include the Investigator's spouse or domestic partner and dependent children. [See 42 CFR Section 50.603 & 45 CFR Section 94.3],

**Research** means any systematic investigation designed to develop or contribute to generalizable knowledge. 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.

**Significant Financial Interest** means holding any management position (e.g, director, officer, trustee, management employee) in a non-Emory entity, or anything of monetary value, including but not limited to, gifts to the Investigator, 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, trade secrets and royalties from such rights); provided, however that 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 or non-profit entities[1].

(d) Income from service on advisory committees or review panels established by and paid for by governmental or non-profit entities[2].

(e) Salary or other Compensation that when aggregated for the Investigator and the Investigator’s spouse or domestic partner and dependent children currently and over the next 12 months are less than $10,000 **UNLESS** the value of the Compensation can be affected by the Investigator’s Research, in which case ANY amount of Compensation shall
be considered to be a Significant Financial Interest.

(f) Equity interests in publicly traded companies[3], excluding mutual funds, that are less than $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value.

(g) Equity interests in a publicly traded companies that are less 1% ownership of the company.

(NOTE: In determining the value of an equity interest, any interests held individually by the Investigator, his/her spouse and dependent children must be added together and the aggregate value used to determine if it exceeds the limits set forth above.)

[See 42 CFR Section 50.603 and 45 CFR 94.3]

**Significant Financial Interest Related to Research** means 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 Related to Research must be reported to the Institutional Official or his/her designee. [See Sections 42 CFR 50.604(c) and 45 CFR Section 94.4(c)].

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[1] Income from non-profit entities that are related to a commercial entity must be reported.
[2] Income from non-profit entities that are related to a commercial entity must be reported.
[3] A publicly traded company is one whose stock is traded on a stock exchange such as NYSE, NASDAQ, etc. All equity holdings in privately held companies related to Research must be reported.

Related Links

- Current Version of This Policy: [http://policies.emory.edu/7.7](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 - p134, 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))
- National Science Foundation (NSF) Regulations at Federal Register, Volume 60, No. 32, July 11, 1995, pages 35822-35823 ([http://frwebgate5.access.gpo.gov/cgi-bin/TTEXTgate.cgi?WAIStocID=703027174324+2+1+0&WAISaction=retrieve](http://frwebgate5.access.gpo.gov/cgi-bin/TTEXTgate.cgi?WAIStocID=703027174324+2+1+0&WAISaction=retrieve))

Contact Information

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<td>Clarification of Policy</td>
<td>Office of Research Administration-Conflict of Interest</td>
<td>404-712-0046</td>
<td><a href="mailto:coi-web@emory.edu">coi-web@emory.edu</a></td>
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Revision History

*Emory University policies are subject to change at any time. If you are reading this policy in paper or PDF format, you are strongly encouraged to visit policies.emory.edu to ensure that you are relying on the current version.*