



Policy 7.24

Institutional Financial Interests Involving Human Subject Research

Responsible Official: VP for Research Administration

Administering Division/Department: Office of Research Administration

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Overview

Emory University is committed to ensuring that its research involving human subjects is conducted with integrity and free from any actual or apparent bias due to institutional financial interests. This policy provides the standards and procedures that Emory University follows when Emory has Significant Institutional Financial Interests that are related to human subject research conducted by its investigators.

Applicability

This document applies to all faculty, staff and students at Emory University who engage in research involving human subjects.

Policy Details

Emory University will seek to eliminate or manage any Institutional Financial Conflict of Interest involving Human Subject Research. This policy does not require that Emory refrain from conducting University business with entities that have a financial relationship with the University; however, certain relationships must be identified promptly and resolved appropriately. The primary goal is to ensure that the welfare of human subjects and the integrity of the research are not compromised.

Emory Policy 4.112 stipulates the procedures used by Board of Trustee members, University Principal Officials, and Key Employees for resolving any Institutional Conflicts of Interest that arise from their personal financial interests; therefore, this policy shall not apply to them.

A. Separation of Administrative Oversight for Human Subjects Research Program

The functions and responsibilities related to administrative, ethical, and scientific oversight of Emory research programs involving human subjects shall be separate from the functions and responsibilities related to the administration and management of Emory's investments and endowment. The criteria that govern the making of Emory investment decisions shall specifically preclude consideration of information related to the University's Human Subject Research activities.

B. Licensed Intellectual Property in Human Subject Research

When Emory licenses its intellectual property (IP), the University may receive equity in a company as a result of a licensing agreement for Emory IP; receive royalties or other fees as compensation for the use of that IP; and/or may receive equity or other financial interest as part of a co-investment in a licensee or related company.

When an investigator at Emory undertakes to perform Human Subject Research on Emory licensed technology or other intellectual property that is being tested for safety or efficacy and the license fees exceed \$100,000 annually or Emory receives equity through the license agreement, Emory's financial relationship with the licensee must be reviewed pursuant to the procedures in Section III, E.

C. Gifts

In compliance with the Emory Gift Acceptance Policies & Procedures, Emory Policy 3.7, any gifts to Emory must be unconditional, in furtherance of Emory's charitable mission, and non-reciprocal. Per the procedures identified in Emory Policy 3.7, any gifts of equity in individual companies will be sold as soon as it can be practically and legally accomplished. These procedures will be used for any gifts of equity in companies that utilize Emory Intellectual Property to produce a drug, device, diagnostic, etc. that is involved in Human Subject Research at Emory.

Emory may receive gifts from corporate donors that may also sponsor research involving human subjects. When a gift meets the Institutional Financial Interest threshold, the gift must be reviewed pursuant to the procedure in Section III, E.

D. Significant Financial Interests of Institutional Leaders

Pursuant to this policy^[1], Institutional Leaders shall recuse themselves from any business decision, allocation of University resources or personnel, approval process, or oversight review process involving a company with which they have a Significant Institutional Financial Interest that is related to Human Subject Research at Emory. If recusal is not possible in order to carry out their University obligations, they must divest the Institutional Financial Interest. Any exception must be reviewed by the Provost and the Vice President for Research Administration, who may request an advisory opinion from the University Institutional Conflict of Interest Review Committee.

- For example, a Department Chair should not review or approve an IRB protocol for Human Subject Research when she has a Significant Institutional Financial Interest in the sponsor or provider of test material in the protocol.

E. Procedures for Identifying and Reviewing Institutional Financial Interests

1. IRB protocols

All human subject research protocols submitted for IRB review must indicate the nature and source(s) of all drugs, devices, or biologics that will be used in the proposed research, and the source(s) of all funding used in supporting the research.

2. Identification of Potential Institutional Conflicts of Interest

a. Licensing Activities

To the best of their knowledge, Investigators shall identify the use of Emory Intellectual Property in Human Subject Research on the IRB application. Those protocols shall be forwarded to the Vice President for Research Administration or his designee for assessment and review.

Additionally, the Office of Technology Transfer shall compile a list that includes:

- (i) all entities in which the University holds an equity interest as part of a licensing arrangement; and
- (ii) a list of technologies sorted by licensee where Emory has received more than \$100,000 in royalties during the last 12 months. These lists shall be updated every six months or as requested by the COI Review Office. Using this list of entities, the COI Review Office will search the IRB databases to determine whether an identified entity is the financial supporter for the study. The COI Review Office shall refer any identified IRB protocols and licensing information to the Vice President for Research Administration. The Vice President for Research Administration, or designee, shall follow the procedures for assessment and review.

b. Gifts

The Office of the Vice President for Health Affairs Development or other appropriate Development Office shall provide to the IRB Department a list of corporate donors that give more than \$500,000 in cash per annum to a Department or Center. On a reasonable basis, the IRB will review the list of donors against a list of active protocols. If a listed Donor is the sponsor or financial supporter of Human Subject Research, the IRB will refer the research and gift proposal for review by the Vice President for Research Administration, or his designee. The Vice President for Research Administration, or designee, shall follow the procedures for assessment and review.

3. Assessment and Review

The Vice President for Research Administration (VPRA) shall make an initial assessment of whether a Significant Institutional Financial Interest related to the research exists and then take the following actions:

- If the VPRA determines that a Significant Institutional Financial Interest does not exist, the disclosing individual shall be notified by the VPRA staff that no action is necessary.
- If the VPRA determines that a Significant Institutional Financial Interest exists but it cannot directly and significantly affect the proposed research, the VPRA shall notify the investigator and instruct him/her how to disclose

the University's relationship in all publications, proposals, consent documents, and presentations.

- If the VPRA determines that a Significant Institutional Financial Interest could potentially directly and significantly affect the research, the VPRA shall request the investigator to provide a detailed written explanation of compelling circumstances why the research should proceed at Emory.

a. Compelling Circumstances

When an Investigator is proposing to perform Human Subject Research for which a Significant Institutional Financial Interest could directly and significantly affect the research, the PI shall be responsible for drafting and submitting to the VPRA a detailed explanation of the compelling circumstances surrounding the research. This explanation must include the steps taken to secure an alternate research site, not affiliated with the University, and the justification for why the alternate research site is inadequate. The PI should also consider including comments that address the Criteria for Evaluating an Institutional Financial Conflict of Interest in Section III, E.3.b.1.

b. University Institutional Conflict of Interest Review Committee

When an Investigator submits an explanation of Compelling Circumstances, the VPRA may send the protocol to an ad hoc independent organization, including an external IRB independent of Emory, or may form an ad hoc committee that includes one member from outside Emory. These experts will formulate a recommendation as to whether an Institutional Financial Conflict of Interest exists and how it could be managed. In reviewing the research, the Significant Institutional Financial Interest, and the explanation of Compelling Circumstances, the Committee will use the Criteria for Evaluating an Institutional Financial Conflict of Interest in Section III, E.3.b.1. The Committee may determine that the Significant Institutional Financial Interest is too great and the research should not occur at Emory, unless divestiture is possible prior to the commencement of the study.

The University Conflict of Interest Review Committee shall review the recommendations of these experts, and make its own recommendation to the Vice President for Research Administration when the research also has any individual conflicts of interest of investigators, which must be separately reviewed under Emory Policy 7.7.

1. Criteria for Evaluating an Institutional Financial Conflict of Interest

- Nature of the research, current phase of development and intentions for subsequent phases
- Magnitude of potential risks to human subjects inherent in the research, and how those risks could be affected as a result of the ICOI
- Degree to which the Institutional Financial Interest could be directly and substantially affected by the research
- Whether the studies involve Emory Intellectual Property that is used as a platform technology or a generic method used broadly
- Likelihood that a societally important development project will be substantially impeded if the research is not performed at Emory

- Societal impact of successful development, relative to potential risk to the university
- Magnitude of potential risks posed to students or trainees engaged in the research project
- The effectiveness of managing, reducing or eliminating the Significant Institutional Financial Interest through recusal, divestiture, or independent oversight of the affected research
- Whether the trial is at multiple sites and, if so, whether the University's role is relatively passive or the site that gathers and/or monitors the data from all other sites
- Whether the University's resources are fundamentally important to the progress of the science or the University investigator is truly uniquely qualified or integral to administer the study
- The proportion of the total subjects in the study that are under the supervision of the University
- The degree of risk to the human subjects involved that is inherent in the research protocol
- In cases where an Institutional Financial Interest involves an Institutional Leader, the following shall also be considered:
 - o the degree of direct and immediate authority that Institutional Leader has over the research and the people involved in the performance and reporting of the research
 - o whether a plan for separation of oversight of the faculty/staff conducting the human subject research by the Institutional Leader with the conflict can be implemented that is both practical and effective while the Institutional Leader remains in the assigned leadership position

2. ICOI Management Tools

If the University Institutional Conflict of Interest Review Committee (UICOIRC) determines that a Significant Institutional Financial Interest exists and may be managed, the Committee must include in its finding a justification as to why Emory and/or its investigator must be involved in the research despite the ICOI. The management plan must require disclosure to the public and to the human subjects enrolled in the study of the Significant Institutional Financial Interest. Additional management tools that may be used to minimize the risk to the University may include:

- Referral of the protocol to an external IRB for review and monitoring.
- An independent monitoring mechanism to be established, which could include any of the following: data safety monitoring board, independent monitor, or independent reviewer.
- Permitting the research to proceed subject to a plan of divestiture of financial interests.
- Permitting only certain procedures and analysis to occur at Emory.
- Requiring a second opinion as to whether the human subjects should participate in the study.

· Other tools as determined by the UCOIRC.

The Vice President for Research Administration must share the findings and any management plan of the UCOIRC with the Institutional Review Board. The Institutional Review Board may require additional tools to protect the welfare of human subjects involved with the study. The IRB shall review the management plan as part of its initial review of a new protocol. If an ICOI arises after initial IRB approval has been granted, the IRB will review the management plan following notice by the UCOIRC.

4. Violations and Sanctions

Failure to report a Significant Institutional Financial Interest, or refusal or failure to cooperate in the management plan of an Institutional Financial Conflict of Interest may be cause for disciplinary action up to and including dismissal. Possible violations of this policy include, but are not limited to, providing false, misleading, or incomplete information.

[1] This policy shall not limit Institutional Leaders' obligations for disclosure and/or management of other financial interests by Institutional Leader that are required by other Emory policies or procedures.

Definitions

Human Subject Research is any research that meets the definitions of "research" with "human subjects," as defined in the Emory Institutional Review Board Policies & Procedures, that requires review and approval by the Emory Institutional Review Board.

Significant Institutional Financial Interest means Emory's

(1) receipt of equity through a licensing agreement when the licensee is the sponsor or financial supporter of Human Subject Research [2] and the licensed technology is the subject the Human Subject Research;

(2) receipt of a cash gift that is more than \$500,000 annually from an entity to be used by a specific Department or Center when the Center/Department's faculty is performing Human Subject Research and the donor is the sponsor or financial supporter of Human Subject Research or

(3) receipt of royalties or licensing fees that exceed \$100,000 annually for technologies being tested or evaluated in Human Subject Research under Emory IRB oversight or its designated IRB.

Significant Institutional Financial Interest for an Institutional Leader includes:

(1) An equity interest or entitlement of equity of any amount in a non-publicly traded company that is the sponsor or financial supporter of Human Subject Research

(2) Consulting fees, advisory board fees, remuneration, honoraria, or gifts that exceed \$100,000 annually from a company that is the sponsor or financial supporter of Human Subject Research;

(3) A fiduciary role in a company that is the sponsor or financial supporter of Human Subject Research; or

(4) Receipt of royalties or licensing fees that exceed \$100,000 annually for licensed technology that is the subject the Human Subject Research.

Institutional Leader is an individual who, because of his or her position with the University, has the capacity to affect, or can reasonably appear to affect, University processes for the design, conduct, reporting, review, or oversight of human subject research. Such officials can include but are not limited to the Vice Presidents, Associate Vice Presidents, Deans, Executive Associate and Associate Deans of Research, Department Chairs, Center Directors, and Directors of Research Administration Units.

An Institutional Financial Conflict of Interest involving Human Subject Research exists when the University Institutional Conflict of Interest Review Committee determines that a Significant Institutional Financial Interest held by Emory University or an Institutional Leader can significantly and directly affect or reasonably appear to affect the institutional processes for the design, conduct, reporting, review, or oversight of human subject research.

[2] 21 CFR Part 312; 21 CFR Part 812

Related Links

- Current Version of This Policy: <http://policies.emory.edu/7.24>
- [Current Version of This Policy](http://policies.emory.edu/7.24) (<http://policies.emory.edu/7.24>)

Contact Information

Subject	Contact	Phone	Email
Clarification of Policy	Conflict of Interest Office	404-712-0046	coi-web@emory.edu

Revision History

- Version Published on: Jun 15, 2011
- Version Published on: Jun 15, 2011 (*General edits and updates within Policy Details and Definitions.*)
- Version Published on: Mar 03, 2011 (*Original Publication*)

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