



Medical College of Georgia

Administrative
Policy Library

Institutional Conflicts of Interest Policy

CITATION REFERENCE

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Abbreviated Title: Institutional Conflicts of Interest Policy

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Policy Statement

Every investigator, employee and other representative performing work for MCG shall disclose any significant institutional financial or other conflict of interest which arises during the course of his or her work to the appropriate Responsible Representative.

Reason for Policy

Consistent with its system for the disclosure and management or elimination of individual conflicts of interest, and to further protect the integrity of our institution, MCG has adopted this policy on institutional conflicts of interest. Institutional financial reward, business relationships and commercial activities are appropriate only to the extent that they further MCG's mission: to improve health and reduce the burden of illness in society by discovering, disseminating, and applying knowledge of human health and disease.

Entities Affected by this Policy

Every investigator, employee and other representative performing work for MCG, concerning any significant institutional financial or other conflict of interest which arises during the course of his or her work

Who Should Read this Policy

Every MCG employee, including faculty and staff, and every representative performing work on behalf of MCG.

Contacts

Contact	Phone	e-mail/URL
Office of Legal Affairs	(706) 721-4018	http://www.mcg.edu/Services/Legal/

Website Address For This Policy

www.mcg.edu/policies/documents/InstitutionalCOI.pdf

Related Documents

MCG Ethics Policy – www.mcg.edu/policies/9001.html

Individual Conflicts of Interest Policy –
www.mcg.edu/policies/documents/IndividualCOI.pdf

Definitions

1. **“Institutional conflict of interest”** means any situation in which the Medical College of Georgia, any of its senior management, a department, school, or other sub-unit, or affiliated foundation or organization, has an external relationship with or financial interest in an individual or company that has a) a financial interest in a faculty research project and/or b) other significant commercial dealings with MCG or its affiliates. The existence or appearance of such conflicts of interest can lead to real or apparent bias in the review or conduct of research or other work on behalf of MCG.

Major types of institutional conflicts of interests:

a. *Equity interests* are those that may create actual or apparent bias in decisions about research or other institutional work where MCG holds relevant equity positions or has royalty arrangements, and the equity or royalties are derived from MCG or its affiliates’ inventions, start-ups, or other institutional technology transfer. An example of potential institutional conflicts of equity interests: Institution transfers technology to a faculty member’s small, private start-up company, retaining an equity position in the company where the stock is not yet traded on the open market. The faculty member may have an individual conflict of interest, and MCG may have an institutional conflict of interest. Both conflicts of interest should be disclosed and managed or eliminated according to policy.

b. *Interests of officials* are those concerning individuals in positions to make decisions with institution-wide implications. These individuals include the President, other senior officers, deans, research center leaders, and members of governing boards. Their duty to report individual conflicts are addressed in MCG’s Individual Conflicts of Interest Policy (see Related Documents, above). Additionally, their external work and activities such as board service, for example, creates potential for institutional conflicts of interest as the officials make decisions that affect MCG and also the external board(s) or entities that they serve.

2. **“Responsible Representative”** of the institution means:

a. Department Chair for faculty and other departmental personnel meeting the definition of investigator;

b. Dean for Department Chair;

c. Provost for Deans (other than Dean, School of Medicine) and other Vice-Presidents;

- d. President for Provost and Dean, School of Medicine;
 - e. University System of Georgia Chancellor for President;
 - f. Chair, supervisor or other officer in leadership chain of command for members of MCG-affiliated service boards and cooperative entities; and
 - g. Institutional official for designee.
3. **"Significant institutional financial interest"** means anything of monetary value, including, but not limited to payments, equity interests (such as stocks, stock options or other ownership interest); and intellectual property rights (such as patents, trademarks, copyrights and royalties from such rights) that, during the next twelve-month period, meets either of these criteria: (i) meets or exceeds one hundred thousand dollars (\$100,000.00) value as determined through reference to public prices or other reasonable measures of fair market value; or (ii) represents 10% or more ownership in any single entity.

Overview

The Medical College of Georgia has in place a system for the disclosure and management or elimination of individual conflicts of interest. Institutional financial reward, business relationships and commercial activities are appropriate only to the extent that they further MCG's mission.

DISCLOSURE OF INSTITUTIONAL CONFLICTS OF INTEREST

Every investigator, employee and other representative performing work for MCG shall disclose any significant institutional financial or other conflict of interest which arises during the course of his or her work to the appropriate Responsible Representative. This disclosure shall be on MCG's "Conflict of Interest Disclosure Form," a copy of which is attached. The Conflict of Interest Disclosure Form shall be signed by the person who completes it. A separate disclosure form is required for each institutional conflict of interest. The disclosure shall be updated by the individual who determines that a conflict of interest may exist immediately as new reportable significant institutional financial or other conflicts of interest are acquired or discovered (in no event less than 30 days after the interest is acquired or the conflict is discovered). If no conflict of interest existed at the time of an initial proposal, project or action but such a conflict arises during the course of the proposal, project or action, the individual who determines that a conflict of interest may exist shall file a Conflict of Interest Disclosure Form as soon as facts creating the conflict become known to him or her.

RESOLUTION OF INSTITUTIONAL CONFLICTS OF INTEREST

The Responsible Representative to whom a disclosure of potential institutional conflict of interest is made shall forward the disclosure form to the Conflicts of

Interest Panel (Membership as per MCG Individual Conflicts of Interest Policy). Upon referral of an institutional conflict of interest from a Responsible Representative of MCG, the Conflicts of Interest Panel shall meet and determine whether a conflict exists and provide guidance and recommendations to manage, reduce or eliminate the conflict. The cooperation of the Responsible Representative and/or the individual who reported the conflict of interest may be solicited by the Panel. The Panel may designate a member to approve administratively any interim conflict management plan submitted by the Responsible Representative. Some examples of possible recommendations, without limitation, are as follows:

1. public disclosure of significant financial interest;
2. establishing a research monitoring process, so that the research can be closely scrutinized to ensure that potential conflicts do not undermine the integrity of the work (consider monitoring of research by independent reviewers);
3. modification or cessation of the research or project (e.g., not conducting proposed research at MCG or halting it if it has commenced);
4. disqualification from participation in that portion of the research that would be affected by the institution's significant financial or other interest;
5. reducing or otherwise modifying the financial (equity or royalty) stake involved; or
6. increasing the segregation between the decision-making regarding the financial and the research activities;
7. obtaining recommendation(s) to manage or eliminate the conflict of interest from an advisor or group that is not affiliated with MCG.

In addition to the examples listed above, the Conflicts of Interest Panel may recommend any other conditions or restrictions which in its judgment would manage, reduce or eliminate the actual or potential conflict of interest, consistent with applicable policies, regulations, and laws.

In its deliberations to manage, reduce or eliminate conflicts of interest, the Panel shall consider the following guidelines:

- MCG will not ordinarily participate in any clinical trial of a drug, device or product if either MCG or the MCG Research Institute, Inc., has a significant financial interest in a company sponsoring the trial. However, if MCG, its investigator, MCGRI, or any of them, hold significant financial interest in a sponsoring company, and MCG is the preferred or only feasible site for a clinical trial, then the Conflict of Interest Panel may recommend that the trial be allowed to proceed at MCG.

As to MCG faculty startup companies in which faculty involvement is limited to equity holdings or rights to equity, MCG may invest in such companies as follows:

- MCG will not act as a lead investor or syndicating agent. All investments, if appropriate, will be as a “passive investor.”
- MCG will not acquire an equity holding greater than 10% of the ownership of a company.
- No MCG officer is to be a member of the board or an officer of the faculty start-up company, or have a personal equity position in the company at the time of MCG’s investment in any of the equity rounds before the company goes public.
- Institutional investments in faculty start-up companies in which MCG faculty have equity interests are subject to case-by-case consideration and approval of the Provost, based upon recommendations of the Conflict of Interest Panel. If the involved faculty member(s) subsequently create MCG-owned intellectual property for which the start-up company seeks a license for commercial use or development, the licensing request will be subject to the review and approval of the appropriate department chair or dean, in consultation with the Vice President for Legal Affairs and Vice President for Research.

All recommendations made by the Conflicts of Interest Panel shall be in writing and shall state the reasons therefore. The recommendations of the Conflicts of Interest Panel shall be delivered to the Provost, who will decide whether or not to adopt or modify them.

The written recommendations together with the Interest Disclosure Form shall be maintained for at least three years after the later of:

- a. the termination or completion of the award, project, action or transaction to which they relate; or
- b. the resolution of any government action involving those records.

In addition to providing recommendations to resolve conflicts of interest, the Conflicts of Interest Panel shall provide recommendations as it deems appropriate for the improvement of this policy.

Except where an institutional conflict of interest concerns his or her actions, the President of the Medical College of Georgia, either directly or through his/her designee, reserves the right to review all decisions regarding management and resolution of institutional conflicts of interest. In the event the President determines that the decision concerning a conflict of interest is incorrect, inappropriate, or inconsistent with applicable law, the President reserves the right to rescind, modify, or reverse such decision.

The Conflicts of Interest Panel and the Provost shall notify the Responsible Representative, the individual reporting the conflict of interest, and other appropriate department, such as Division of Sponsored Program Administration, Office of Human Research Protection, Purchasing, etc., of their recommendations and decisions concerning the management or elimination of the reported conflict. Where applicable, the Division of Sponsored Program Administration shall be responsible for notifying the sponsor of the conflict of interest and MCG's determination as to the management or elimination of the conflict within 60 days after the conflict is reported.

Process/Procedures

None beyond the guidelines described in “Overview,” above.

Responsibilities

The responsibilities each party has in connection with the *Institutional Conflict of Interest Policy*, are:

(Party)	(Responsibility)
Vice President for Legal Affairs	Responsible for management and oversight of Institutional Conflicts of Interest Policy
Responsible Representative	See number 2 in “Definitions,” above
All Medical College of Georgia faculty, employees, and students	Responsible for adhering to the Administrative Policies of the Medical College of Georgia.

Forms

Conflict of Interest Disclosure Form (attached)

Appendices

None

MEDICAL COLLEGE OF GEORGIA Conflict of Interest Disclosure Form

(Applicable to all Sponsored Project Proposals and other significant individual and institutional conflicts of interest)

Name: _____

Name and relationship of Family Member with Conflict (if applicable): _____

Department/Unit: _____

School/Unit: _____

Proposal Submitted to (Sponsor): _____

Proposal Title: _____

A. Reason for Form: I am completing this form pursuant to one of the following:

_____ Institutional conflict of interest per MCG Institutional Conflicts of Interest Policy;

_____ Annual disclosure as required by MCG Individual Conflicts of Interest Policy;

_____ Update of my annual conflict of interest disclosure;

_____ In connection with my involvement as investigator in a proposal entitled:

_____ where the sponsor is _____.

PLEASE READ THE FOLLOWING CAREFULLY: Check this item ONLY IF you have no reportable significant financial or other possible conflicts of interest pursuant to MCG Conflicts of Interest Policies.

_____ I HAVE NO SIGNIFICANT FINANCIAL OR OTHER SIGNIFICANT CONFLICT OF INTEREST THAT I AM REQUIRED TO REPORT. *If you check this item, then proceed to PART E, complete that section and submit this form to your Department or Unit Supervisor or Dean:*

B. Type of Interest: I have read and understood the Conflicts of Interest Policies of the Medical College of Georgia. I am disclosing the following type of conflict of interest (check at least one) and attaching supporting documentation (in an envelope marked confidential) that identifies the business enterprise or entity involved and the nature and details of the interest:

1. Significant financial interest. Individual's significant financial interests are defined as anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interest); and intellectual property rights (e.g., patents, trademarks, copyrights and royalties from such rights). "Investigator" includes Investigator and the Investigator's spouse or dependent children. [See MCG Conflict of Interest Policy for items not included.]

_____ Salary or other payment for services (e.g., consulting fees or honoraria).

_____ Equity interests (e.g., stocks, stock options, or other ownership interests).

_____ Intellectual property rights (e.g., patents, trademarks, copyrights, and royalties from such rights).

____ Other significant financial interest of the individual or family member that possibly could affect or be perceived to affect the results of the research or other scholarly activities funded or proposed for funding or other work on behalf of MCG. This interest is described as follows:

2. _____ Other individual conflict of interest: _____

3. _____ Institutional Conflict of Interest: _____

C. Detailed information concerning significant financial interests (individual or institutional):

1. Please identify the business enterprise or entity (hereafter called "company") involved and the amount of the financial interest:

1a. Name of company: _____

1b. Amount of financial interest: _____

2a. Are you an officer of the company in which you have a financial interest? _____

2b. If so, what are your responsibilities and how much time do you dedicate to this activity?

3a. Are you a member of the governing Board of Directors for the Company? _____

3b. If so, please describe the general nature of the Board, your responsibilities, and your time commitment as a board member:

4a. Are you a consultant for or otherwise compensated by the company for advice, lectures, workshops, etc.? _____

4b. Please describe the activities for which you receive compensation: _____

4c. Date and period the activity is conducted: _____

5a. Do you own stock in the company? _____

5b. Number or percentage of shares owned: _____ of possible _____ # or shares.

5c. Percentage of ownership: _____

5d. The stock is subject to (Check all that apply):

- _____ Anti-dilution provisions
- _____ Registration restrictions
- _____ Shareholders' agreements

5e. Is the stock publicly traded? _____

6a. Does the company plan to submit proposals for federal funding? _____

6b. If so, is it for research which would be performed at MCG? _____

6c. If so, is it for research that you would supervise at the company? _____

7a. Does the company intend to sponsor, from its own resources, any work at MCG? _____

7b. If so, will it be necessary or preferable for the work to be performed in your laboratory?

8. Describe the significance of the research identified in 5 or 6 above to any commercial product that the company will sell or manufacture:

9a. Do you intend to involve any MCG student in your funded work? _____

9b. If so, for each student, please describe the nature of the work :

10. Please list all MCG faculty and staff who will assist you in this work and indicate whether each individual has a potential conflict of interest:

Name:	Conflict?
_____	_____
_____	_____
_____	_____
_____	_____

11. If the study is a clinical trial, has this conflict of interest been disclosed to the IRB?

D. Proposed Resolution: Please describe to the members of the MCG Conflict of Interest Panel the recommendations of you and your Chair for managing, resolving or eliminating the potential conflict of interest described above. _____

E. Further I agree and affirm:

- That I have read the Individual Conflicts of Interest and Institutional Conflicts of Interest policies of MCG;
- That the above information is true to the best of my knowledge;
- That I will update this disclosure immediately if the circumstances above change during the period of the award, either on an annual basis, or as new reportable significant financial interests are obtained. In any event at a minimum I will update this disclosure annually;
- Where applicable, I will cooperate in the development of a conflict of interest "resolution plan."
- I will comply with any conditions or restrictions imposed by the Medical College of Georgia to manage, reduce, or eliminate actual or potential conflicts of interest or forfeit the award.

Signature of Individual completing form: _____ Date: _____
(Original signature only – a "per" signature is not acceptable.)

Signature of Chair or Dean: _____ Date: _____