

Human Research Protections Program (HRPP)

Institutional Responsibilities and Policies Regarding Conflict of Interest

The institution has policies and procedures that require the reporting of Conflicts of Interests and Conflicts of Commitments for all employees. The Medical College of Georgia, Medical College of Georgia Health System, Inc., and the Physician's Practice Group Conflict of Interest Policy will be posted in January 2008. The policy is posted below for information purposes.

POLICY STATEMENT

All individuals performing work on behalf of the Medical College of Georgia should understand their duty to avoid actual and apparent conflicts between their official obligations and personal interests. (See for examples MCG Ethics Policy, MCG Outside Professional Activities Policy and Board of Regents Policies 802.14, 802.16, 802.1601, 802.1602)

Board of Regents policy provides that employees shall make every reasonable effort to avoid apparent and actual conflicts of interest, and requires every employee to continually monitor, evaluate and manage his or her financial and professional affairs to ensure the absence of conflicts of interest. (See BOR Policy 802.14B and C) In addition, state and federal laws and regulations govern the disclosure and management of conflicts of interest: Georgia law prohibits state employees from participating in certain transactions that could create conflicts of interest. Federal regulations require institutions to establish standards to promote objectivity in sponsored research through investigator disclosure and institutional management of financial conflicts of interest.

The mere existence of a conflict of interest does not imply wrongdoing. However, disclosing individual conflicts of interest so that they can be managed or eliminated is critical to protect the integrity of the work in furtherance of our institution's mission. This policy is intended to assist MCG employees and other representatives in disclosing, managing and eliminating conflicts of interest.

REASONS FOR POLICY

To (1) ensure the integrity and objectivity of research and other scholarly activities by faculty, staff, and other representatives performing work for the benefit of MCG through the disclosure and management of individual conflicts of interest; (2) assist in identification and reporting of conflicts of interest; and (3) promote compliance with state laws related to conflicts of interest of public officers and employees

ENTITIES AFFECTED BY THIS POLICY

All full-time and part-time MCG employees, including faculty and staff; and other representatives performing work on behalf of MCG, concerning any significant financial conflict of interest or other conflict of interest of his/her own or spouse and dependent children which arises during the course of his or her work

WHO SHOULD READ THIS POLICY

Human Research Protections Program (HRPP)

Every MCG employee and other representative performing work on behalf of MCG.

CONTACT FOR POLICY QUESTIONS

Office of Legal Affairs, (706) 721-4018, <http://www.mcg.edu/Services/Legal/>

RELATED DOCUMENTS AND LINKS

I. DISCLOSURE AND MANAGEMENT OF CONFLICTS OF INTEREST

A. DEFINITIONS

1. "Conflict of interest" means any situation in which it reasonably appears that a significant financial interest or other personal interest could compromise the integrity of work to be performed for MCG (for instance without limitation: in the design, conduct, or reporting of activities funded or proposed for funding by a sponsor; in the vendor selection process; in hiring or employment decisions; in research approval processes). A conflict of interest includes, without limitation, apparent or actual bias in the work to be performed for MCG, created by an individual's personal relationships, or by an individual's or family member's significant financial interest or other interest in a company that does business with, competes or may compete with the Medical College of Georgia.
2. "Investigator" means the principal investigator, sub-grantee, contractor, co-investigator, and any other person (e.g., post-doctoral fellows and visiting scientists) at MCG who is responsible for the design, conduct, or reporting of research or scholarly activities funded or proposed for funding by a sponsor. For purposes of this policy, "investigator" shall include the investigator's spouse and dependent children.
3. "Employee" means any full-time or part-time employee of MCG to include faculty and staff.
4. "PHS" means the Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated. See 42 Code of Federal Regulations Part 50, Subpart F.
5. "Research" means a systematic investigation designed to develop or contribute to generalizable knowledge.
6. "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 all Deans (except Dean of School of Medicine) and other Vice-Presidents; and

Human Research Protections Program (HRPP)

d. President for Provost and Dean, School of Medicine

e. Chair, supervisor or other officer in leadership chain of command for members of MCG-affiliated service boards and cooperative entities

f. USG Chancellor for President

7. "Significant financial interest" means 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). The term does not include:

- salary, royalties or other remuneration from MCG;

- income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities (in connection with approved outside professional activity);

- income from services on advisory committees or review panels for public or nonprofit entities (in connection with approved outside professional activity); or

- an equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests: [i] does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and (ii) does not represent more than a 5% ownership in any single entity; or

- other salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the next twelve-month period.

EXCEPTION: When the proposed project involves human subjects and approval from the Institutional Review Board, the above monetary thresholds do not apply. In human subject research, the threshold for required conflicts of interest disclosure is any dollar or stock amount above zero.

B. PROCEDURE FOR DISCLOSURE OF CONFLICTS OF INTEREST

Every investigator, employee and other representative performing work for MCG shall disclose any significant financial conflict of interest or other conflict of interest of his/her own or spouse and dependent children 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 as "Exhibit A". The form shall be signed by the person who completes it. A separate disclosure form is required for each project and for each conflict of interest.

Human Research Protections Program (HRPP)

Every investigator must submit a completed and signed disclosure form to the appropriate institutional representative prior to the time any research grant, contract, or other extramural proposal is submitted for review to the Division of Sponsored Program Administration. Investigators must also certify that appropriate disclosures have been made and that any potential conflicts of interest have been resolved before beginning related work. A certification is included on the standard MCG grant routing sheet and must be signed by the investigator. This certification is also required on the Human Assurance Committee (HAC) and Office of Human Research Protection (OHRP) routing forms for research protocols, including internally and externally funded proposals (certification requires disclosure and resolution of potential conflicts).

The disclosure shall be updated by the investigator immediately as new reportable significant financial interests 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 the initial proposal but such a conflict arises during the course of the project or proposal, the investigator shall file a Conflict of Interest Disclosure Form as soon as facts creating the conflict become known to him or her, and shall provide copies to all applicable offices such as the HAC, OHRP, DSPA, etc. Investigators added during the course of a project must also disclose their conflicts of interest as acquired or discovered. At a minimum, every investigator, faculty member, and member of MCG senior leadership shall complete a Conflict of Interest Disclosure Form annually, to certify awareness and compliance with institutional policy.

C. PROCEDURE FOR RESOLUTION OF CONFLICTS OF INTEREST

The Responsible Representative to whom a disclosure of a potential conflict of interest is made shall forward the disclosure form to the Conflicts of Interest Panel, a body of not less than five members appointed by the Provost, one of whom shall not be an employee of MCG. General members shall serve three-year staggered terms. Additionally, at least one ex-officio member shall be appointed to serve a longer term at the discretion of the Provost.

Upon referral of a conflict of interest from a Responsible Representative of MCG, the Conflicts of Interest Panel shall review the submission, determine whether a conflict exists and provide guidance and recommendations to manage, reduce or eliminate the conflict. The cooperation of the Responsible Representative and 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:

- a. public disclosure of significant financial interest;
- b. monitoring of research by independent reviewers;
- c. modification of the research plans;

Human Research Protections Program (HRPP)

- d. disqualification from participation in that portion of the research that would be affected by the significant financial interest;
- e. divestiture of significant financial interests by the investigator; or
- f. severance of relationships that create actual or potential conflicts of interest;
- g. 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.

Additionally, IRB members with a conflicting interest may not participate in the review of research except to provide information requested by the IRB, and must leave the meeting room during discussion and voting.

All recommendations made by the Conflicts of Interest Panel shall be in writing and shall state the reasons therefore. The management plan and recommendations shall be delivered to the Responsible Representative; to the individual who reported the conflict; and to the Provost, who will decide whether or not to adopt or modify them. In addition, the HAC may disapprove a proposal even if the Conflicts of Interest Panel approves the management plan; or may require more frequent continuing review.

The written management plan(s) and recommendations together with the Conflict of Interest Disclosure Form shall be maintained for at least three years in the Office of the Provost after the later of:

1. the termination or completion of the award, action or transaction to which they relate; or
2. 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.

Appeals of the Provost's decisions concerning conflict management may be submitted to the President of the Medical College of Georgia. Except where a conflict of interest involves his or her actions, the President, either directly or through his or her designee, reserves the right to review all decisions regarding management and resolution of 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 who reported the conflict, and the appropriate related office, such as the Division of

Human Research Protections Program (HRPP)

Sponsored Program Administration or Office of Human Research Protection, of their recommendations and decisions concerning the management of the reported conflict of interest. If the conflict involves sponsored research, when required, the Division of Sponsored Program Administration shall be responsible for notifying the sponsor and any other appropriate related office, such as the OHRP and/or HAC, of the conflict of interest and MCG's determination as to its management within 60 days after the conflict is reported.

D. FORMS

Significant Conflict Disclosure Form

II. STATE LAW PROVISIONS

A. Georgia law provides that any public official or state employee who directly or indirectly solicits, receives, accepts or agrees to receive anything of value by inducing the reasonable belief that the giving of the thing will influence his/her performance or failure to perform any official action commits the crime of bribery. (See Official Code of Georgia Annotated Section 16-10-2) This felony crime is punishable by imprisonment for up to twenty years, a maximum fine of \$5,000, or both.

B. Georgia law provides that it is a crime punishable by imprisonment for one to five years for an employee or officer of a political subdivision or agency thereof (for example, the Board of Regents or system institution such as MCG) to sell real or personal property to certain political subdivisions of the state, including that employee's political subdivision or agency. Certain exceptions are provided. (See O.C.G.A. Section 16-10-6)

C. Georgia law states that it is unlawful for any full-time employee, either for himself/herself, or on behalf of any business, or for any business in which that employee or his/her family member has a substantial interest, to transact business with the agency which employs him/her. This law applies to Board of Regents employees including employees of institutions in the University System. Certain exceptions are provided. (See O.C.G.A. Sections 45-10-20 through 45-10-28)

D. Georgia law requires that each vendor who, either directly or through another person, makes a gift or gifts to a public employee exceeding in aggregate \$250.00 in value per calendar year must file a disclosure report by February 1 with the State Ethics Commission listing the amount and date of receipt, vendor's name and mailing address, and the name, address and position of each employee receiving such gift. (See O.C.G.A. Section 45-1-6)

E. Georgia law requires all state employees to file annual disclosure statements of their own and family members' business transactions with any state agency, except those in which the amount of a single transaction does not exceed \$250 and the aggregate of all transactions for the calendar year does not exceed \$9,000. This disclosure must be submitted before January 31 annually via forms provided by the Secretary of State. These forms are available from the MCG Human Resources Department and are provided to all employees on or about the first of each calendar year. Employees who transact business with the State and fail to file the annual disclosure

Human Research Protections Program (HRPP)

statement may be subject to civil penalties, including restitution, a fine of up to \$10,000 and termination of employment. (See Official Code of Georgia Annotated Section 45-10-26).

The law does allow, however, for full-time employees of the Board of Regents to serve as members on governing bodies of private, non-profit, educational, athletic or research related foundations and associations which are organized for the purpose of supporting institutions of higher education in Georgia and in which in furtherance of this purpose may transact business with such institutions or with the Board of Regents of the University System of Georgia. Such foundations and associations would include, but are not limited to, MCG Research Institute, MCG Foundation, Allied Health Practice Group, Dental Practice Group, Nursing Practice Group, Physicians Practice Group, MCG Foundation and MCG Health Inc. (See O.C.G.A. Section 45-10-23)

III. PENALTIES FOR NON-COMPLIANCE

Any employee who violates this policy may be subject to disciplinary action up to and including dismissal. Any other MCG representative who violates this policy may be subject to removal from the position.

If an investigator's failure to comply with this policy has biased PHS-funded research, MCG shall promptly notify the PHS Awarding Component of the corrective action taken or pending. MCG shall provide information on conflicts of interests and their management, reduction or elimination, upon request, to the federal Department of Health and Human Services (HHS). Should HHS determine that a PHS-funded clinical research project to evaluate the safety or effectiveness of a drug, medical device, or treatment was designed, conducted, or reported by an investigator with a conflict of interest that was not disclosed or managed, then the investigator(s) must disclose the conflict of interest in each public presentation of the results of the research.

Penalties for violations of Georgia law, such as incarceration and fines may be in addition to any disciplinary action taken by the Medical College of Georgia.

Human Assurance Committee

The HAC will make a determination regarding the level of disclosure required in the consent document, as well as other measures to reduce or eliminate the potential conflict. If the HAC determines additional disclosure or measures to protect subjects are necessary, they will request the additional revisions to the protocol and/or consent document and/or conflict management plan as part of the review process. The HAC has the final authority in regards to human subject research (appropriate disclosures) and conflict of interest.

Chesapeake Research Review, Inc.

The CRRI will make a determination regarding the level of disclosure required in the consent document, as well as other measures to reduce or eliminate the potential conflict. If the CRRI determines additional disclosure or measures to protect subjects are necessary, they will request the additional revisions to the protocol and/or consent document and/or conflict management plan as part of the review process. The CRRI has the final authority in regards to human subject research (appropriate disclosures) and conflict of interest.