



EMORY
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SCHOOL OF
MEDICINE

Office of the Dean

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July 15, 2004

Charles B. Nemeroff, M.D., Ph.D
Reunette W. Harris Chair & Professor of Psychiatry & Behavioral Sciences
4000 Woodruff Medical Building
Emory Campus

RE: Relationship with GlaxoSmithKline
Conflict of Interest Case 2004-021-01
NIMH U-19 grant: The Emory GSK NIMH Collaborative Mood Disorders
Institute – basic science and clinical research program

Dear Dr. Nemeroff:

The Conflict of Interest Committee reviewed your relationship with GlaxoSmithKline and your NIMH collaborative grant described above. As you know, the Committee is charged with the responsibility of determining whether a faculty member has potential conflicts of interest or commitment - real or apparent; whether they should be managed; and, if necessary, assisting the faculty member by developing a plan that minimizes or dissolves the conflicts.

In performing this review of a faculty member's relationships with outside parties, the Committee applies the standards enumerated in various University policies, and the Committee used these policies, common sense, and "best practices" in reviewing your relationships. For your reference, I have summarized the applicable policies and guidelines on the attached pages. I also call your attention to the fact that all the federal funding agencies view conflicts with heightened scrutiny and audits. Further, a university cannot be seen as applying different standards on a conflict of interest and research integrity for federal and industry-sponsored research, and the Committee applies at least the federal standard to all.

REVIEW OF YOUR RELATIONSHIP WITH GLAXOSMITHKLINE

The Committee understands that you serve on the GlaxoSmithKline Paroxetine Advisory Board and provide advice to GSK on their products that are already on the market. For these services, you receive approximately \$15,000 annually. You do not have any stock options or other equity interests in GSK. Please correct the record if this is not correct.

You are the PI for the NIMH-Emory-GSK U-19 Center Grant. The original application envisioned an Administrative Core and an Animal/Assay core and seven research projects.



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An equal opportunity, affirmative action university

After peer review, the Administrative and Animal/Assay Cores were funded with three research projects: Animal Models of Fear and Anxiety (Michael Davis PI); Cytokine-Induced Depression: A Rhesus Monkey Model (██████████ PI); and Clinical Assessment of Novel Antidepressant/Anxiolytics (██████████ PI, NIH). Dr. ██████████ is the PI for the Animal/Assay Core, and you are the PI for the Administrative Core.

The Administrative Core provides the administrative resources for all of the individual research projects that include: statistical consultations, scheduling meetings among the investigators and executive committee, scheduling use of common facilities, scheduling routine equipment maintenance, internal budgeting for the entire Center, maintaining financial records for the entire Center, archiving of data, statistical analysis (Dept of Biostatistics RSPH), maintenance of a common reference database as well as obtaining copies of relevant articles for distribution, development and maintenance of a Center Web-site, assistance in preparation of slides and posters for presentations, final manuscript and report preparation, preparation of non-competitive renewal applications and distribution of reports and reprints. As the PI, you are responsible for overseeing the operation of the entire project. You are responsible for research coordination and planning, resource allocation, and being the liaison among the various research sites and director of the executive committee.

The Committee found that you have a significant financial interest in GSK because your consulting fees are more than the *de minimis* amount established by Emory's University Policy, the AAMC guidelines, and PHS regulations, which is currently \$10,000 annually. GSK is a collaborator on the grant and will be providing the study drugs for the grant. This significant financial interest in GSK creates a conflict of interest. The University Conflict of Interest Policy specifies that if the financial interest of the investigator in the research sponsor or the technology being studied could potentially bias the investigator's judgment in the conduct of the research, a conflict of interest exists.

In order to manage this conflict of interest, the Committee requires that you keep your consulting fees from GSK to an amount equal to or less than \$10,000 on annual basis throughout the grant period, its renewals, and final collection of data. This procedure is necessary because your role as PI is necessary for the grant to continue. In doing so, you will eliminate your conflict of interest as defined by Emory policies and PHS regulations. You must clearly certify on your annual disclosure form that you do not receive more than \$10,000 from GSK. Please be aware that most journals and conferences require the disclosure of any relationship(s) between authors and sponsors or suppliers of study drugs, equipment, etc.

It is very important for you to understand that the finding of a personal conflict of interest does not in any way imply "bad behavior" on the part of the faculty member. To the contrary, conflicts are inevitable in our complex technology transfer and funding environment and many other of our outstanding and completely ethical faculty are managing similar conflicts. However, University policy and increasingly stringent federal law mandate that the faculty member has a responsibility to provide full

disclosure and seek in advance approval and conflict management plans for all consulting and research activities that might raise even the appearance of conflict, and also to recognize that when he/she chooses to enter the commercial market privately for financial gain in areas that overlap with his/her academic pursuits, the consequences may include restrictions that hinder what the faculty may then do in academic research and in training students and fellows. The University has a mandatory joint responsibility with the faculty member either to develop an impeccable plan to manage the conflict or to eliminate it – to preserve the public trust in the knowledge discovered and disseminated by the University, and also to protect both the University and the faculty member from even the appearance of data bias, self-dealing, or other forms of undue influence. It is often the case that the perception of a conflict by the public is more harmful than any actual actions taken by the faculty member or the University.

If you have any questions, please do not hesitate to contact Dr. [REDACTED] Chair of the Committee, at [REDACTED]. Please sign and date the enclosed copy of this letter and return it to: Brenda J. Seiton, J.D., Assistant Dean for Administration, [REDACTED] WHSCAB.

Sincerely,


Claudia R. Adkison, J.D., Ph.D.
Executive Associate Dean/Faculty Affairs & Administration

I agree to abide by the management plan described above.

Charles B. Nemeroff, M.D., Ph.D.

Date

CRA/bjs

cc: R. [REDACTED], M.D., Ph.D.
Ms. [REDACTED]

APPLICABLE POLICIES AND REGULATIONS THAT DEFINE CONFLICTS OF INTEREST AND COMMITMENT

Article IX of the University Bylaws requires employees of the University to disclose any conflicting interest in any transaction involving the University and requires that they not use their personal influence in connection with, participate in, or act on the matter.

The **University Policies and Procedures for Faculty Members Involved in Sponsored Research and Technology Transfer** is the University's policy on conflict of interest in the conduct of research and, as indicated in the text, is based upon federal regulations. The underlying concept is that faculty should generally avoid private financial entanglements with the external entities that may be affected by their research to protect their own reputations and the University's reputation for research integrity from any actual or perceived taint arising from allegations of data bias, private inurement, and tax code violations. This policy:

- Allows faculty, under appropriate circumstances, to hold equity in, serve on a scientific advisory board of, and be the PI for research sponsored by a research sponsor or licensee of Emory technology. The evaluation of the circumstances to determine whether they are "appropriate" is the major function of the Committee, along with developing management plans when possible. The Committee takes the position that a conflicted faculty member generally may not serve as an officer or board member in his/her company, although it recognizes that during the very most preliminary phases when no outside capital is involved, the "company" is virtual, and the "company" is the faculty member, some flexibility is necessary.
- Applies to the Investigator (faculty member), co-investigators, collaborators, and the investigator's spouse and dependent children. Therefore, the investigator has a duty to report potential conflicts of all these individuals.
- Requires the Investigator to report in advance to the Dean and also in some cases to OTT any proposal:
 - To a sponsor from which the Investigator receives \$10,000 or more in compensation, equity of 1% or valued at \$10,000 or more, or royalties from the licensing of Emory technology;
 - To evaluate the sponsor's technology when the Investigator receives \$10,000 or more or 1% equity from the sponsor;
 - When the Investigator/sponsor is asking for a waiver or preferential reduction of the University IDC and the Investigator receives \$10,000 in compensation or 1% equity in the sponsor;
 - To purchase equipment or other materials from a vendor in which the Investigator holds 1% equity or receives \$10,000 or more in compensation; or
 - That further develops technology already licensed to a company in which the Investigator holds equity or receives compensation.

- Requires the Dean's Office to review relationships between investigators and sponsors to ensure that:
 - The nature and scope of research is appropriate and consistent with the Investigator's academic and research interests;
 - Any financial interests of an Investigator that could affect the design, conduct, or reporting of research or educational activities is disclosed and eliminated, as appropriate;
 - Graduate students, postdoctoral researchers, and other Emory personnel are assigned appropriate duties consistent with their status or position; and
 - Research sponsors' access to University equipment, supplies, and intellectual property rights is appropriate and consistent with Emory's legal, policy, financial, and reputational interests.

- Provides some examples of management tools, such as, in increasing severity:
 - Public disclosure of the financial arrangement in publications and presentations;
 - Monitoring of the project by independent reviewers;
 - Disqualification of the Investigator from participation in the project;

- Divestiture by the Investigator and separation of the Investigator from the company/sponsor (elimination of the conflict).
- Prohibits a conflicted Investigator from conducting research involving human subjects except in certain unique circumstances.

The **University Conflict of Interest Policy** is a broad policy that covers many types of relationships. It:

- Prohibits employees from engaging in any business or financial relationship, transaction, or event that may be viewed, internally or externally, as a conflict of interest between the employee and an outside party and that would result directly or indirectly in financial benefit accruing to the employee. The outside parties include, without limitation, contractors, consultants, vendors, suppliers, and others.
- Provides several examples, including disclosure of the University's non-public information for personal profit and acceptance of gratuities or special favors valued over \$40.

The **University Policy on Consulting, Teaching, and Other Services Outside the University** allows schools to implement their own more detailed policies. The University policy:

- Requires faculty members to disclose in advance all consulting agreements, in writing, to their respective Chairs and Deans for review and approval to ensure that no conflicts of interest exist and that the arrangements do not interfere with the faculty members' duties and responsibilities to the University.
- Prohibits faculty members from using University resources, which includes letterhead, the Emory name and trademarks, computers, the Emory networks, Emory space, equipment, personnel, and other facilities, for their private activities.

The **School of Medicine Policies on Commitment, Private Consulting, and Other Extraordinary Contributions** provide that:

- A full-time faculty member is bound to provide 100% of his/her professional effort to the School, University, and Emory medical practice plans.
- A faculty member may engage in private consulting up to 20% of his/her professional effort with the prior approval of the Chair, Dean, and, if necessary, Conflict of Interest Committee. All consulting agreements must be submitted in writing and approved before execution. The review of the agreement is done in detail for compliance with School, University, and Emory Healthcare policies.
- The policy does not set a monetary limit on the amount of money a faculty

member may receive as compensation for such private external activities.

The University **Guidelines for the Responsible Conduct of Scholarship and Research** has many parts, but in one part it instructs faculty dissertation and research directors to encourage their students to be open and to share ideas and information with other members of the scholarly community, and it establishes the University ownership of data even beyond the ownership that is implicit in the employment association.

The **Public Health Service and the Secretary of Health and Human Services**, the governmental body to which NIH reports, enacted regulations which established standards and procedures to be followed by institutions that apply for research funding from the PHS to ensure that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements or contracts will not be biased by any conflicting financial interest of those investigators responsible for the research. Specifically, the regulations require institutions to:

- maintain a written, enforced policy on conflict of interest
- designate an institutional official to solicit and review financial disclosure statements from each investigator
- manage, reduce, or eliminate the investigator's Significant Financial Interests that would reasonably appear to be affected by the research and those interests in entities whose financial interests would reasonably appear to be affected by the research. Significant Financial Interests are defined as:
 - salary, royalties, or other payments for services (e.g., consulting fees or honoraria) that are more than \$10,000 annually
 - equity interests (e.g. stocks, stock options, or other ownerships interests) that are valued at more than \$10,000 or that represent more than 5% interest ownership
 - intellectual property rights (e.g., patents, copyrights, and royalties from such rights)

The **Association of American Medical Schools (AAMC)** published guidelines on the Oversight of Individual Financial Interests in Human Subject Research in December 2001. These guidelines recommend that:

- a financially interested individual may not conduct human subjects research unless compelling circumstances exist
- thresholds levels for significant financial interests are defined as:
 - consulting fees, honoraria, travel expenses, or gifts from a company related to the research that exceed \$10,000 annually;
 - equity interests of any amount in a non-publicly traded company related to the research;
 - equity interests in a publicly traded company that are valued at more than \$10,000 or represent more than 5% ownership;
 - royalty income or the right to receive future royalties under a patent license or copyright, where the research is directly related to the licensed technology or work; or
 - service as an officer, director, or in any other fiduciary role for a company

related to the research, whether or not remuneration is received for such service.

The **Association of American Universities (AAU)** also published guidelines on the oversight of potential conflicts of interest in research in October 2001. They adopted a guidelines that do not allow researchers to have financial interests in research involving human participants unless there are “compelling circumstances” to justify an exception.