

President's Advisory Commission on Research Integrity and Professional Conflict Management

Executive Summary

In November of 2008, Emory University President James Wagner charged the President's Advisory Commission on Research Integrity and Professional Conflict Management (the "Commission") to "evaluate the completeness and appropriateness of our policies, the effectiveness of our practices, and the mettle of our culture concerning financial and professional conflicts of interest." A group of 10 faculty members were initially appointed to the Commission by the President, chaired by Paul Root Wolpe, Director of the Emory Center for Ethics. The Emory faculty members included Dennis Choi, School of Medicine; Kathy Griendling, School of Medicine; Connie Kertz, Goizueta Business School; Chris Larsen, School of Medicine; Polly Price, Law School; John Stuhr, Emory College; Elaine Walker, Emory College; and Carl Washington, School of Medicine (Max Cooper withdrew from the Commission, leaving it with 9 members). The faculty was ably assisted by its staff, including Michael Johns, Chancellor of Emory University; David Wynes, Vice President for Research Administration; Steve Sencer, Deputy General Counsel; Tara Adyanthaya, Associate General Counsel; and Anita Bray, of the Office of the Chancellor.

The President's charge to the Commission to examine the policies, practices, and institutional culture around financial and professional conflicts at Emory was a challenge. The Commission chose a multi-pronged approach. First, the Commission reviewed all the existing policies related to conflict(s) of interest ("COI") and conflict(s) of commitment ("COC") at Emory, as well as some of the literature on COI and COC in academic institutions. The Commission was then divided into four subcommittees: "Policies," with the responsibility to make recommendations concerning the written policies at Emory; "Practices I: How we capture information," with the responsibility to make recommendations concerning faculty reporting about conflicts; "Practices II: How we respond," with the responsibility for making recommendations concerning how the university manages conflicts; and "Institutional Culture," with the responsibility for making recommendations concerning improving the general attitude towards COI at Emory. Subcommittees carried out their work and reported back to the entire Commission.

The Commission met monthly, and its work included primary and secondary research of the literature; hearings and interviews with faculty and administrators; exploring best practices at other universities through policy research and consultation; an open forum for the Emory community to express its concerns and advice; an invitation to the Emory community to email suggestions and comments to the Commission; and a questionnaire sent to the Deans of the Schools at Emory to determine each School's actual policies and procedures. A Draft Report was created and circulated and edited by the Commission members and staff.

The Commission hearings revealed concern for, and much thoughtful consideration of, issues surrounding COI and COC at Emory. While commentators sometimes had conflicted or contradictory attitudes and concerns, some major themes included:

- 1) A need for policies and their justifications to be more clearly and systematically communicated at Emory;

- 2) The burdensome nature of the current system of paper submission of forms, and the multiple and repetitive requirements for reporting;
- 3) Conflicting and ambiguous policies;
- 4) Lack of integration and coordination of information;
- 5) Lack of a central resource for understanding how COI are investigated and resolved and lack of transparency in the system;
- 6) Long turnaround times for many submissions; and
- 7) A sense that the University is becoming overly restrictive with its policies and attitudes.

Emory University has extant policies for most aspects of COI and COC. There are both University-wide policies and School-specific policies; the university policy on “Private Consulting”, for example, specifies that “Each school and college is responsible for adopting policies and procedures for private consulting by its faculty.” Seven of the nine Emory Schools have complied with this policy charge. In general the system requires reporting of all significant external financial interests that may be related to Emory research, as well as any other potential or actual conflicts of interest, to the Department Chair or Dean, though the Dean has ultimate responsibility for managing COI. The University policy specifies only a few minimums to be included in individual School policies: “At a minimum, each faculty private consulting arrangement must be disclosed in writing to and reviewed by the Department Chair and Dean in advance to determine whether any actual or potential COI exists and to assure that the arrangement does not interfere with the faculty member’s duties and responsibilities to the University.” Different schools handle the scope and detail of this reporting quite differently.

A revised University-wide policy generated by the Office of Research Administration (Policy 7.7: *Policy for Investigators Holding a Financial Interest in Research*) and a revised School of Medicine policy (*Policy on Industry and Other External Relationships*) were released during the Commissions deliberations. In addition, a new University-wide Conflict of Interest Committee has been established under the Vice President for Research Administration.

The Commission identified a number of “best practices” in University policies. The Commission believed the best among the existing individual School COI policies provide clear definitions of “conflict of interest” versus “conflict of commitment,” explain why the COI policy benefits the faculty member as well as the University and the public, and articulate clear responses to violations of the policy. Other components of “best practices” include:

Education, Training, and Clarity:

- The policy defines COI and COC, and gives examples or guidance on disclosure requirements and what is permissible.
- Steps are taken to explain the policies, including information sessions provided to faculty, and a designated person within the School to whom to address questions about compliance with the policy.
- The policy explains why the policy benefits the faculty member as well as the University and the public.
- The policy addresses how COI of the principal investigator affect graduate students and fellows.

Disclosure and Reporting:

- The School policy requires both annual reporting and “ad hoc” or “transactional” (as new situations arise) reporting.
- The policy addresses how the reported information is handled, including a confidentiality provision.
- The policy provides a timeline for administrative response.
- The policy provides an appeal procedure.

Compliance and Consequences:

- The policy specifies a procedure to manage conflicts as they are identified.
- The policy specifies a process for following-up on compliance.
- The policy specifies consequences for violations.
- The policy specifies a process for enforcing reporting, as well as a process for enforcing sanctions.

Given the existing policies and the significant recent work by the University, in particular the Office of the Vice President for Research Administration and the Dean’s Office of the School of Medicine, the Commission’s recommendations are offered as suggestions to add value to a system that is already positioning itself as a model for academia.

As the Commission focused primarily on research and faculty COI, the members strongly urge the University to convene a committee to examine in more detail staff COI, which are not covered in detail in this report.

The Commission’s recommendations are as follows:

A. Revise the University-wide conflict of interest and commitment policy to more fully articulate a coherent and shared set of basic values, setting forth minimum standards to which School policies must conform

It is imperative that the University standardize and make consistent its COI policies. General principles and the values underlying COI and COC policies should be articulated, with clear definitions of terms and illustrative examples. The 22 different University-wide policies should be condensed and made consistent, and should set more minimum standards. The existing multiple School policies should conform to the rewritten University policies. Then all policies, both University-wide and policies from individual Schools, should be posted on a central resource.

B. The University-wide policy should clearly communicate which classes of employees are subject to the policies and what constitutes prohibited, circumscribed, and permitted activities

The University-wide policy should provide clarity as to what activities are permitted or prohibited and under what circumstances. Right now, the terminology used is often ill-defined and the circumstances to which the policy applies can be ambiguous. Many of these issues are addressed in the recently-approved Emory University School of Medicine Policy

on Industry and other External Professional Relationships, and the Commission encourages University leadership to consider incorporating elements of that Policy into a University-wide policy.

C. Require effective faculty and staff education, including new faculty and staff orientation, and encourage mentoring on conflicts of interest and commitment

Many people reported to the Commission that they were never briefed on COI or COC policies at Emory, that there was no continuing education about these issues, and that new faculty and graduate and professional students often had no idea what these policies were or their purpose. It is recommended that Emory develop a meaningful, ongoing educational process that assists in promoting a culture that successfully balances self interest, the University's mission, and community interests.

D. Include procedures for safeguarding interests of subordinate faculty and employees, students and trainees

Senior faculty and high-level Staff have tremendous influence on students, trainees, post-doctoral fellows, and/or subordinates. Special care should be taken to disclose potential conflicts, limitations, and alternatives to the affected person. Decisions always must be governed by the student's or trainee's best interests consistent with Emory's mission and should not be influenced by an interest in outside commercial and professional activities.

E. Improve reporting and disclosure mechanisms

The Commission recommends that the current process be strengthened and streamlined. Some suggestions include:

- 1) providing for a two-tiered reporting process that considers the risk of improper influence and provides for a random auditing procedure (see below);
- 2) implementing newly developed software that will simplify reporting and review of potential conflicts;
- 3) improving efficiency and response time to increase confidence that the system has been designed to balance legitimate concerns about conflicts with faculty members' professional obligations;
- 4) addressing legitimate concerns about confidentiality in reporting; and
- 5) providing for appropriate transparency consistent with the public interest.

The Commission favors a two-tier approach to faculty reporting, where faculty members must report, prior to engagement, financial interests and outside activities with significant potential for real or perceived COI/COC, allowing time for management strategies to be implemented if necessary. The Commission was split on the issue of full faculty income disclosure for non-professional activities. Should faculty be required to reveal all non-professional sources of external income (e.g., the fee they get for umpiring little league, or income from the etchings they do as a hobby) to the University, even if it results in very modest income? The majority felt that a specified threshold income amount should be set, and below that faculty should not be required to reveal to the university non-professional

income generated off-hours. However, at a minimum, all professional activities that generate income should be summarized by the faculty member in his/her annual COI/COC report.

The Commission strongly recommends that Emory utilize an integrated database to track and flag potential COI, as well as to track University review of these conflicts. Such a database has multiple advantages, in that it reduces the burden of paperwork, makes compliance monitoring simpler, allows faculty to track and confirm reporting, and simplifies preparation of the Annual Report. The Commission has been informed that an excellent new electronic reporting system – eCOI -- is being developed and should be fully operational by the beginning of the 2009-2010 academic year. It is the understanding of the Commission that, as currently configured, eCOI does not have the capacity to integrate with other databases such as that used by the IRB or with PeopleSoft. The Commission recommends that this system be evaluated for its ability to fulfill the above suggested guidelines, and efforts be made to assure the overall integration of all relevant databases at Emory.

Confidentiality must be balanced with transparency. Several faculty members complained that overly strict requirements for disclosure may be unnecessarily damaging to their reputations, such as when certain industry affiliations unfairly color legitimate relationships. In contrast, others noted that Emory's national reputation requires the application of systematic regulations and disclosure, and emphasized the importance of transparency and stakeholders' interest in full disclosure (e.g, patients should know if their doctor consults for a particular device company, students should know if their research supports a faculty member's start-up company, etc.). University policies must weigh the value of disclosure and transparency, against potential invasion of privacy and the possibility of public misinterpretation.

A common management tool is to require those with COI to disclose the nature of the conflict to interested parties. Disclosure does not, however, minimize the potential of improper influence arising from a conflict, it merely reveals it. Unfortunately, too often disclosure wrongly is regarded, by both the individual disclosing and the managing institution (e.g., a university, or a professional journal), as sufficient to eliminate the problem of COI. In the Commission's view, disclosure should be seen strictly as a first step in COI management.

F. Require prompt and efficient management of reported external professional activity, with swift and fair enforcement of compliance

All Schools must develop and periodically review their policies. Not all Schools are currently in compliance with University policy in that regard. In the central University policy, the responsibilities and accountability of the Faculty, Deans and the Provost with respect to review of external professional activity must be clearly described. Administrative review must be efficient and timely. Confidentiality of review should be assured, with disclosure to the public carefully structured and the conditions for such disclosure well thought-out and clearly understood by the faculty.

The Commission heard from many faculty and staff that once a management plan has been identified, there is little or no follow-through to ensure compliance. The university should develop a system of monitoring, though the details must be worked out carefully in a committee dedicated to that process. Finally, sanctions should be clear and uniformly

enforced, and subject to appeal. The Commission therefore recommends that the university develop a clearly defined set of progressive sanctions, which could include a letter from the Dean asking for cease and desist; review of research findings; written reprimand; disallowance or limiting outside activities; freezing of research accounts; suspension without pay; demotion; and termination for cause. In extraordinary circumstances, the faculty member should be able to seek an appeal from the Provost or Executive Vice President for Health Affairs.

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