



The fundamental mission of the FSM to advance the health of the public is critically dependent upon trust in the integrity of the research, education, and patient care that our faculty provide. A productive relationship between the academic medical community, industry, and other external entities, however, is an important factor in realizing the full potential of biomedical research and its ultimate translation to patient care. Pharmaceutical, device, and biotechnology companies, therefore, frequently collaborate with basic scientists and physician investigators at academic medical centers to achieve breakthroughs in medical research and to perform clinical trials to establish the efficacy and safety of promising new therapies. To maintain the public trust, it is imperative that these relationships not be or appear to be influenced by factors other than the pursuit of knowledge and the best interests of the patient. To ensure that these relationships are founded upon these factors, the FSM has adopted a Conflict of Interest and Professional Integrity Policy based upon the recommendations of the AAMC and a Disclosure Policy that requires all of its faculty to report all external, compensated professional activities no matter the amount. These disclosures include but are not necessarily limited to payments from industry for consultancies, speaking arrangements, promotional activities, equity, stock options, royalties, grants for research and education, and external fiduciary positions. With the firm belief, moreover, that transparency is essential in maintaining the public trust; these disclosures will be posted on the FSM website and updated on a regular basis.



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PREAMBLE

The vitality and integrity of medical research and education are absolutely critical to the health of the public. The relationship between the academic medical community and industry, moreover, is essential to realize the full promise of biomedical research. To maintain the trust of the public and to be compliant with all pertinent legal requirements, however, this relationship must be firmly based upon the principles of integrity, full disclosure, and the appropriate management, reduction, or elimination of conflicts of interest when they occur in the domains of research and education. The following document describes the policy established by the Feinberg School of Medicine (FSM) to achieve these goals in addition to those set forth in the University's Faculty Conflict of Interest and Conflict of Commitment Policy (University Faculty Policy). The FSM Policy is intended as a supplement to the University Faculty Policy.

DEFINITIONS

Conflict of Interest

A "conflict of interest" exists when there is a divergence between a faculty member's private interests and his/her professional obligations, such that an independent observer might reasonably question whether the faculty member's professional actions or decisions are determined by any consideration other than the best interests of the school, their students, trainees, or their patients.

Covered Individuals

For the purposes of this policy, "covered individuals" includes all full time, part time, and research faculty, their spouses, children, and parents.

Disclosure Requirements

All covered individuals are required to disclose both on an annual basis and on a transactional basis to the Office for Regulatory Affairs the sources and the amounts of all income received from outside professional/commercial activities as defined in the University Faculty Policy. There is no de minimus threshold for disclosure. This requirement does not include income derived from institutions or practice plans affiliated with Northwestern University and/or Feinberg School of Medicine, income from mutual funds not directly managed by the covered individuals, nor honoraria received from



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another academic institution for academic activity. Royalty income or the right to receive royalties under a patent or other intellectual property license (except for royalties

received for academic publications) must be disclosed. FSM reserves the right, moreover, to require a faculty member to provide to the Dean's Office copies of consulting agreements, contracts, and other documentation related to income received for outside professional/commercial activities.

HUMAN SUBJECTS RESEARCH

All faculty engaged in human subjects research must disclose to the IRB and in the consent form the existence of a conflict of interest he/she or any member of the research team may have relevant to the research project. This disclosure must include the existence of all financial interests of a covered individual that are related to the research project. Conflicts of interest that are deemed to be significant or potentially significant by the Dean for Regulatory Affairs will be referred to the FSM Conflict of Interest Committee (COIC), and the faculty member's participation in the project will be approved, modified, or disallowed by this committee. The precise wording in the consent form should be determined by the IRB but should include the fact that the conflict has been reviewed by the COIC of FSM and determined by both the IRB and the COI not to pose any additional significant risk to the welfare of the subjects or to the integrity of the research. There is a presumption, moreover, against participation in human subjects research by a significantly conflicted investigator that can be overcome only by the demonstration of "compelling circumstances" to the FSM COIC.

EDUCATION

Continuing Medical Education (CME)

All requests for industry support and receipt of funds for CME activity should be coordinated and overseen by the CME office of the FSM or the CME offices of its affiliated institutions. The CME offices are responsible for auditing compliance with the standards of the Accreditation Council for Continuing Medical Education (ACCME). Educational programs offered by any commercial activity, moreover, should be offered only by ACCME-accredited providers according to ACCME standards. The use of fully accredited but independent CME offices is permitted only with the approval of both the relevant chair and the Dean for Regulatory Affairs.



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Participation in Industry-Sponsored Programs

With the exception of settings in which academic investigators are presenting the results of their industry-sponsored studies to peers and there is opportunity for critical

discussion, faculty are strongly discouraged from participating in industry-sponsored speakers' bureaus. When faculty participate in industry-sponsored, FDA-regulated programs, payment must be at fair market value and all such activity should be reported to the FSM within one year of the date of participation.

Faculty, students, and trainees should not attend non-ACCME accredited industry events described as continuing medical education nor accept payment or gifts for attending industry-sponsored meetings.

Industry-Sponsored Scholarships and Other Educational Funds for Trainees

All scholarships and other educational funds from industry should be reported to the FSM Office for Regulatory Affairs. The Dean for Regulatory Affairs, after consultation with the appropriate department chair when relevant, will evaluate and select the recipient of such funds with no involvement by the donor industry. There must be no quid pro quo for the acceptance of such funds.

Gifts

The acceptance of gifts of any value from industry by faculty, students, and trainees is prohibited.

Access by Pharmaceutical and Device Manufacturer Representatives

Access by pharmaceutical representatives to individual faculty should be restricted to nonpatient areas and nonpublic areas and should occur only by appointment or invitation of the physician. Involvement of students and trainees in such meetings should occur only for educational purposes and only under the supervision of a faculty member. Only appropriately credentialed device manufacturer representatives should have access to patient care areas and should occur only by appointment or invitation of the physician. They may not be present during any patient care interaction unless prior disclosure to and consent by the patient has occurred and then only to provide in-service training or assistance on devices and equipment.



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Food

With the exception of food provided in connection with ACCME-accredited programming and in compliance with ACCME guidelines, industry-supplied food to faculty, students, and trainees should not be permitted.

Professional Travel

Faculty, students, and trainees may not directly accept travel funds or reimbursement of expenses from industry other than for legitimate contractual services.

Ghostwriting

Faculty, students, and trainees are prohibited from allowing their professional presentations of any kind, oral or written, to be ghostwritten by any party, industry or otherwise.