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## **A. PREAMBLE**

The fundamental mission of the Northwestern University Feinberg School of Medicine (“Feinberg”) is to advance the health of the public through education and research, which ultimately translates into improved patient care. An important component in realizing this mission is a productive relationship between the academic medical community, Industry, and other external entities. Therefore, pharmaceutical, device, and biotechnology companies 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 in this mission, however, it is imperative that these relationships not be or appear to be influenced by factors other than the pursuit of knowledge and the best interest of the patient.

To ensure that these relationships are founded upon these factors and to comply with the regulations of the U.S. Department of Health and Human Services (“DHHS”), Feinberg has adopted this Disclosure and Professional Integrity Policy (“the Feinberg Policy”) based primarily upon the recommendations of the Association of American Medical Colleges (“AAMC”). The goal of the Feinberg Policy is to foster an environment in which all Feinberg faculty (regular and research, full-time and part-time, contributed services, health system clinician, and regular-lecturer) and students/trainees can advance public health and build relationships while maintaining objectivity, integrity, and public trust.

Additional policies governing pharmaceutical samples, formulary and medical device evaluation as well as purchasing decisions and referrals are maintained by our affiliated hospitals and practice groups.

For questions related to this policy, or additional compliance guidance, please contact the Feinberg Vice Dean for Regulatory Affairs or the Feinberg Director of Compliance.

## **B. APPLICATION OF THE FEINBERG POLICY**

The Feinberg Policy is intended to be a supplement to the [Northwestern University Policy on Conflict of Interest and Conflict of Commitment](#) (“NU COI Policy”) and the [Northwestern University Policy on Conflict of Interest in Research](#) (“NU COIR Policy”).

While the Feinberg Policy applies to all Feinberg faculty (regular and research full-time and part-time faculty, contributed services faculty, health system clinician faculty, and regular-lecturer faculty) (“faculty”), as well as students/trainees, certain provisions of the Feinberg Policy vary with respect to applicability, as set forth below.

- 1. Full-Time and Part-Time (Regular and Research) Faculty:** All sections apply.
- 2. Contributed Services Faculty, Health System Clinician Faculty, and Regular-Lecturer Faculty:** The following sections apply:
  - A. Preamble
  - B. Application of the Feinberg Policy

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- C. Definitions
- D.1. Disclosure of Outside Professional Activities and Conflict of Commitment – Annual Disclosure
- D.2. Disclosure of Outside Professional Activities and Conflict of Commitment – Transactional/Research-Related Disclosure
- D.3. Disclosure of Outside Professional Activities and Conflict of Commitment – AACME and non-AACME Activities
- D.4. Disclosure of Outside Professional Activities and Conflict of Commitment – Disclosure Review and Conflict Management
- D.5. Disclosure of Outside Professional Activities and Conflict of Commitment – Faculty Interactions and Use of Students/Trainees in Outside Professional Activities
- E.2.(b) Professional Integrity – Physician Consulting, Advisory Boards, Speaking Engagements, and Similar Compensated Activities – Ghost Writing Section
- F. Reporting of Potential Misconduct or Violations of Feinberg Policy

**3. Students/Trainees:** “Students/ Trainees” includes all students of Northwestern University while engaging in activities at Feinberg, as well as all housestaff members (residents and fellows) in McGaw Medical Center of Northwestern University training programs. The following sections apply to students/trainees:

- A. Preamble
- B. Application of the Feinberg Policy
- C.3. Definitions – Industry Section
- D.4. Disclosure of Outside Professional Activities and Conflict of Commitment – Faculty Use of Students/Trainees in Outside Professional Activities
- E.1. Professional Integrity – Gifts and Business Courtesies
- E.2.(b) Professional Integrity – Physician Consulting, Advisory Boards, Speaking Engagements, and Similar Compensated Activities – Ghost Writing Section
- E.2.(c) Professional Integrity – Physician Consulting, Advisory Boards, Speaking Engagements, and Similar Compensated Activities – Student/Trainee Outside Professional Activities Section
- E.3. Professional Integrity – Attendance at Educational Programs
- E.4. Professional Integrity – Training and Education Regarding the Use of Medical Devices
- E.5. Professional Integrity – Meals
- E.6. Professional Integrity – Industry-Sponsored Scholarships and Fellowships
- E.7. Professional Integrity – Use of Letterhead
- E.8. Professional Integrity – Relationships with the Investment Community
- E.9. Professional Integrity – Educational Grants and Donations
- E.10. Professional Integrity – Access by Industry Representatives
- F. Reporting of Potential Misconduct or Violations of Feinberg Policy

With respect to this policy, all faculty and students/trainees are expected to act in a manner that avoids any potential or perceived Conflict of Interest.

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## **C. DEFINITIONS**

**1. Conflict of Commitment.** A situation where an individual engages in outside activities, either paid or unpaid, that interferes with his/her primary obligation and commitment to Northwestern University (“NU”).

**2. 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, his/her students/trainees, or his/her patients.

**3. Industry.** For purposes of this policy, the term “Industry” includes medical device and equipment; pharmaceutical manufacturers and distributors; biotechnology firms; health insurance companies; and, others that provide or could provide products and services directly related to the provision of health care and directly affecting the provision of health care.

**4. Investigator.** Anyone responsible for the design, conduct, or reporting of research, regardless of title or position, and their immediate family members.

**5. Outside Professional Activities.** An outside activity is any paid or volunteer activity undertaken by a staff, faculty member, or student/trainee outside the scope of his/her regular NU duties. Outside Professional Activities may include consulting, participation in civic or charitable organizations, working as a technical or professional advisor or practitioner, or holding a part-time job with another employer, whether working in one’s NU occupation or another.

Please refer to the [NU COI Policy](#) and [NU COIR Policy](#) for additional information.

## **D. DISCLOSURE OF OUTSIDE PROFESSIONAL ACTIVITIES AND CONFLICT OF COMMITMENT**

### **1. Annual Disclosure**

Feinberg administers an online [Annual Disclosure Survey](#) on behalf of itself and its affiliated hospitals and practice groups for those individuals designated by these entities. All Feinberg regular and research full-time and part-time faculty, contributed services faculty, health system clinician faculty, regular-lecturer faculty, and certain other faculty are required to disclose online both on an annual basis and when there is a material change in an interim period the sources and the amounts of all income received from Outside Professional Activities. These disclosures include, but are not necessarily limited to:

- Service on Boards of Directors
- Ownership or Investment Interests
- Compensation received from:
  - Industry Relationships

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- Intellectual Property Rights or Interests

In addition, Feinberg requires faculty to disclose voluntary or non-compensated activities, and compensation received for expert witness testimony, medical legal testimony, legal consulting, or other similar professional services.

There is no *de minimis* threshold for disclosure. All Outside Professional Activities related to the health care industry are to be reported, no matter the payment amounts. This disclosure requirement does *not* include compensation received from hospitals or practice groups affiliated with NU and/or Feinberg, research grant amounts, or research-based salary support related to a specific sponsored research project through NU or affiliated institutions. In addition, clinical income generated from contributed services, health system clinician, or regular-lecturer faculty member's private practice is also *not* included. Also excluded from disclosure requirements are activities related to and/or compensation received relative to lectures, seminars, teaching engagements, or service on advisory committees or review panels relating to federal, state, or local government agencies, an institution of higher education as defined in [20 U.S.C. 1001\(a\)](#), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Feinberg reserves the right to require a faculty member to provide to the Feinberg Vice Dean for Regulatory Affairs copies of consulting agreements, contracts, and other documentation related to income received for Outside Professional Activities.

The process for review of a faculty member's disclosures and implementation of appropriate conflict management plans, if applicable, is set forth via process flows (available on the [Policy Links](#) page of the [Office for Regulatory Affairs](#) website, under the Joint Affiliates subsection).

Because transparency is essential for maintaining the public trust, disclosures will be posted to individual [Faculty Profiles](#) on the Feinberg website and updated on an annual basis. Disclosures will be posted by category:

- Service on Boards of Directors
- Industry Relationships
  - Consulting/Related Activities
  - Ownership or Investment Interests
  - Royalty Payments and Inventor Share
  - Medical Record Consultation/Expert Witness Testimony

At the present time, it is not Feinberg's practice to post specific payment amounts or compensation ranges on the Feinberg website, although Feinberg may do so in the future.

The annual survey process is managed by the Office for Regulatory Affairs. All disclosure survey launch communications will be communicated via e-mail; therefore, each faculty member is required to have a current, individualized e-mail address on file with the Feinberg Faculty Affairs Office. The disclosure system may be accessed throughout the year for interim updates of

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significance. A full description of the annual survey process is available on the [Annual Disclosure Survey](#) page of the [Office for Regulatory Affairs](#) website.

Failure to comply with disclosure requirements will lead to sanctions, up to and including administrative suspension of activities, loss of faculty appointment, department or unit financial penalties, or dismissal from the University.

## **2. Transactional/Research-Related Disclosure**

The University and external research sponsors seek to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research will be free from bias resulting from financial interests.

Research-related conflict of interest requirements include required training and ongoing disclosure of specific financial interests throughout the year between the annual faculty disclosures. For those involved in University research, please refer to the [NU COIR Policy](#) for specific information and guidance regarding the requirements around and processes for training, disclosure, review, reporting, management, monitoring, and non-compliance.

In accordance with federal regulations,<sup>1</sup> proposals for research funding may not be submitted by the University, on behalf of an investigator pending full Investigator compliance with the obligations detailed in the [NU COIR Policy](#). The University may hold acceptance of research funding for the same reason.

## **3. ACCME and Non-ACCME Activities**

Feinberg expects all faculty to comply with the ACCME disclosure requirements when speaking at ACCME-accredited events. Additionally, Feinberg requires all faculty to disclose their current external professional activities at the beginning of all lectures and seminars with students, residents and fellows to avoid the perception of potential conflicts of interest.

## **4. Disclosure Review and Conflict Management**

Feinberg faculty annual disclosures are reviewed by Feinberg Division Chiefs, Department Chairs, and the Feinberg Vice Dean for Regulatory Affairs and his designees to determine whether conflict management is indicated or whether a conflict of commitment may exist. Annual disclosures may also be reviewed for the same purpose by a Joint Affiliate Disclosure Review Committee, comprised of compliance leadership from Feinberg and its affiliates.

## **5. Faculty Interactions and Use of Students/Trainees in Outside Professional Activities**

Feinberg faculty are required to disclose their current external professional activities at the beginning of all lectures and seminars to avoid the perception of potential conflicts of interest. The Department of Medical Education has created slide templates to be completed and used as the second slide in any didactic presentations.

Student/trainee involvement in faculty enterprises may provide the potential for substantial

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<sup>1</sup> See 42 CFR Part 50, Subpart F and 45 CFR Part 94.

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benefits to the education and career development of the student/trainee. Such involvement needs to be guided to avoid conflicts of interest or interference with the student/trainee's primary educational and research duties. Per the [NU COI Policy](#), as part of NU's commitment to the academic pursuits and integrity of its students/trainees, the Dean's office requires advance notice and approval of student/trainee engagement in faculty enterprises through receipt and signature of the [Student-Faculty Agreement – Student Engagement in Faculty Enterprises](#). The Dean's Office will also query students/trainees engaged in activities such as those covered under this Agreement on an annual basis for the duration of the work to ensure students/trainees are engaged voluntarily in meaningful work that does not interfere with their academic progress.

Faculty must disclose consulting and enterprise activities as required on Conflict of Interest disclosures, and student/trainee engagement in these activities should be explicitly reported. Students/trainees subject to NU Conflict of Interest disclosure requirements must also disclose their activity in faculty consulting and enterprise activities.

## **E. PROFESSIONAL INTEGRITY**

Not all scenarios that one may encounter are addressed in the following pages. One is, therefore, strongly encouraged to contact the Office for Regulatory Affairs with any questions or concerns. Note to Physicians: This Handbook is consistent with the Northwestern Memorial HealthCare (NMHC) Professional Integrity Handbook with respect to topics addressed under both documents. Physicians with roles at NMHC, however, should also refer to the NMHC Professional Integrity Handbook, which is available at the following address: [2014 NMHC Handbook](#).

### **1. Gifts and Business Courtesies**

A gift or business courtesy includes any good, service, or other item of value given to a person without that person paying money or giving something of comparable or equal value for the good, service, or item. Gifts and business courtesies include, by way of example and without limitation, the following: cash, checks, gift certificates, securities, property, favors, prizes, services, personal travel, personal discounts, supplies, equipment, referrals, employment, food, tickets to plays, concerts, sporting events, golf outings, or any other entertainment events or hospitality.

Neither a faculty member nor a student/trainee, nor their immediate family members may solicit or accept gifts or business courtesies of any value from vendors/Industry, except as noted in Section 3 (iii). This prohibition includes, but is not limited to:

- Acceptance or personal use of a vendor's facilities, equipment, or vacation home;
- Personal trips, vacations, hotel, or resort accommodations;
- Birthday or other gifts in recognition of a life event;
- De minimis office items (e.g., pens, notepads, mugs, calendars); or
- Any item that takes into account the volume or value of referrals, purchases, or other business generated.

Any gift or business courtesy given to an immediate family member of a faculty member or

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student/trainee is also prohibited if the faculty member or student/trainee could not accept the gift directly in accordance with this Feinberg Policy. The prohibition discussed in this paragraph does not apply to the following:

- If the faculty member or student/trainee pays for the gift or business courtesy (e.g., a faculty member or student/trainee can go to a sports event with an Industry representative if he/she pays for his/her own ticket). The amount that you pay, however, should be consistent with the fair market value of the gift or business courtesy; and, items otherwise expressly allowed in this Feinberg Policy.

As a general rule, if a faculty member or student/trainee receives a gift, he/she must return it. However, gifts such as holiday gift baskets or thank you gifts such as food baskets, flowers, or souvenirs may be donated, disposed of, or shared with the faculty member's or student/trainee's department when returning it is impractical. Prior to sharing, the faculty member or student/trainee must remove all Industry identification. Vendors and Industry representatives should be requested not to send gifts in the future.

Similarly, neither a faculty member nor a student/trainee, nor their immediate family members may give gifts or business courtesies of any value to referral sources.

Please contact the Office for Regulatory Affairs prior to the acceptance of any gifts from Industry to support research. Requests to accept offers of unrestricted educational grants and fellowships from Industry must be submitted to the Feinberg Vice Dean for Regulatory Affairs via the online Request for Approval Form available on the [Resources - Conflict of Interest and Professional Integrity](#) page of the [Office for Regulatory Affairs](#) website. It is mandatory that the accepting division or department has sole authority for determining the curriculum and selecting recipients of such grants. If approved, the relevant Department will have sole responsibility for determining the curriculum and selecting the recipient, with no involvement by the donor. There must be no *quid pro quo* for the acceptance of such funds. Acceptance of gifts or courtesies may also need to comply with affiliate requirements.

## **2. Consulting, Advisory Boards, Speaking Engagements, and Similar Compensated Activities**

Faculty may enter into arrangements to provide consulting, medical directorship, product development input, advisory committee participation, teaching/speaking engagements, or other professional services to outside entities for which compensation is received. However, all arrangements must:

- Be memorialized in writing;
- Reflect fair market value compensation for legitimate, reasonable, and necessary services; and,
- Not inappropriately influence the faculty member's Feinberg activities.

(a) Speakers' Bureaus. With the exception of settings in which academic Investigators are presenting results of their studies to peers and there is opportunity for critical discussion, faculty members are strongly discouraged from participating in Industry-sponsored



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speakers' bureaus. Should a faculty member choose to participate in a speakers' bureau, the content and format of the presentation should be educational and must adhere to all [U.S. Food and Drug Administration](#) ("FDA") requirements.

- (b) Ghost Writing. Faculty members and students/trainees may not author or co-author articles in which their name or Northwestern's or NMHC's name is used without their substantive contribution. If Industry employees are co-authors, then this should be made known. There should be full disclosure of the role of each author.
- (c) Student/Trainee Outside Professional Activities. Students/trainees of Feinberg may not participate in outside professional activities with Industry at any time during their training unless the student/trainee seeks and receives written permission from the Feinberg Vice Dean for Regulatory Affairs.

### **3. Attendance at Educational Programs**

Except as allowed under section E.4 (*Training and Education Regarding the Use of Medical Devices*) of this policy, clinical faculty and students/trainees may only attend Industry-funded medical education programs if they fit one of the following categories:

- (a) The program is an [Accreditation Council for Continuing Medical Education](#) ("ACCME") accredited program;
- (b) The program is sponsored by a Feinberg-affiliated institution or Feinberg *and* approved by the Feinberg Vice Dean for Regulatory Affairs;
- (c) The program is part of a professional society meeting that follows ACCME standards; or,
- (d) The program is one that the Division Chief or Department Chair believes to be important for the academic or clinical mission of the faculty member and/or the education of the student or trainee. Following such attestation, the approval of the Vice Dean for Regulatory Affairs must be obtained. Attendance by students at such events must be approved by the Vice Dean for Education.

Educational conferences and programs do not include meetings that deal solely with marketing of a vendor's product or service. A vendor may not pay for the registration fee, travel or lodging or provide other support to attend meetings that deal solely with marketing of the vendor's products or services or where the purpose of the meeting is to view the vendor's products or equipment that are being considered for purchase.

When attending educational programs, faculty and students/trainees shall abide by the following:

- (i) Program Faculty. Subject to compliance with this Feinberg Policy, faculty and students/trainees may serve as a presenter, speaker, moderator, or otherwise provide a substantial educational role for a third-party educational conference, meeting, or

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program and may accept a reasonable honorarium and reimbursement for their own transportation, lodging, and meal expenses relating to the conference. Such compensation and reimbursement must be paid by the conference sponsor, and not by Industry. Faculty and students/trainees must ensure that no Industry representative influences the content of their presentation and that there is appropriate disclosure of any financial ties to Industry, consistent with the rules of the third-party sponsor and the ACCME.

- (ii) Attendees. If faculty or students/trainees are attending a third-party conference only as an attendee (including as a key opinion leader) and not as a bona fide speaker, presenter, or moderator of the conference or unless they are receiving medical device manufacturer-sponsored training or education on a device currently in active use, they may not accept reimbursement from Industry for the program registration fee, transportation, lodging, meals, or other expenses of attending the program or compensation for time spent at the event.
- (iii) Conference-Related or Approved Meals and Receptions/Nominal Gifts. Faculty and students/trainees may participate in a meal or reception sponsored by Industry if the event complies with the guidelines of the ACCME. The meal or reception must be modest in value and conducive to discussion among those participating in the event. The amount of time at any such meals or receptions must be clearly subordinate to the amount of time spent at the conference's educational activities. One may accept a gift from Industry provided in connection with a paid educational conference or program as long as the gift is of nominal value and is generally available to all conference attendees. For example, one can accept a cloth bag given to all registrants to carry conference materials or a pen donated by Industry and made available to all attendees. One may not, however, use or display the gift at Feinberg.
- (iv) Attendance by Spouse or Guests. Under no circumstances may faculty or students/trainees accept reimbursement for transportation, lodging, or meals for the cost of their spouse or other guest(s) unless the spouse or guest has a bona fide purpose for attending the program.
- (v) Location. Conferences must be held in locations that are conducive to the effective transmission of knowledge, which could include, but are not limited to, a hotel or other commercially available meeting facility, medical institution, laboratory, corporate office, or other training facility.

Feinberg requires faculty to use the [Feinberg Office of Continuing Medical Education](#) ("Feinberg Office of CME") to sponsor all on-campus CME educational events.

#### **4. Training and Education Regarding the Use of Medical Devices**

Feinberg and its affiliated hospitals and practice groups recognize that the [FDA](#) mandates training and education to facilitate the safe and effective use of certain medical technology. Additionally, proper training in and awareness of new and innovative medical technology may contribute to

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better and/or more cost-effective patient care. However, the activities surrounding training provided to faculty and students/trainees may raise at least the appearance of impropriety. To ensure that faculty members and students/trainees receive appropriate training free from inappropriate influences over their clinical decision-making, prescribing, and purchasing decisions, they must adhere to the following guidelines regarding attendance at medical device manufacturer-sponsored training sessions:

- 4.1 Faculty and students/trainees may attend medical device manufacturer-sponsored training and education programs in order to further their knowledge on the subject(s) presented. Such programs must contain objective scientific and educational information that will benefit patients. In advance of the trip, you should inform your supervisor that you plan to attend the medical device manufacturer-sponsored training or education.
- 4.2 Training and education programs must be conducted in settings that are conducive to the effective transmission of knowledge, such as a hotel, other commercially available meeting facilities, medical institutions, laboratories, or other training facilities.
- 4.3 Faculty and students/trainees may accept reimbursement for reasonable travel, lodging, and other expenses in connection with a training program at an appropriate location.  
NOTE: No reimbursement for travel, lodging, and meal expenses may be accepted if the purpose of the travel or meeting is to view clinical equipment or products that are under consideration for purchasing but have not yet been purchased.
- 4.4 Faculty and students/trainees may only accept associated hospitality in the form of modest meals and receptions. Any meals and receptions provided in connection with the training program must be subordinate in time and focus to the educational/training purpose(s) of the program.
- 4.5 Faculty and students/trainees may not allow a medical device company to pay for meals, hospitality, travel, or other expenses for their spouse or other guests who do not have a bona fide professional interest in the information being provided at the training program.

## **5. Meals**

Industry representatives are not permitted to provide food on-site at Feinberg. If a faculty member or student/trainee attends a meal to discuss Feinberg-related matters with Industry representatives, they must pay for their own meal.

During professional conferences off-campus, meals, such as lunches, refreshments, and receptions that are included in the conference fee and available for all attendees are appropriate.

Food may be accepted from Industry representatives in the following limited circumstances:

- 5.1 Off-Campus Educational Conferences or Professional Society Meetings: Faculty and students/trainees may accept meals and attend receptions for off-campus educational conference, training, or professional meeting with the requirements that:

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- (a) The meals and receptions are modest, incidental, and subordinate to the educational content or bona fide business purpose of the meeting, with most of the time dedicated to the educational or business purpose;
- (b) Industry must have given the support to the professional society or conference organizer;
- (c) The support is disclosed; and,
- (d) Industry representatives do not participate in meetings and discussions.

5.2 Medical Devices: Faculty and students/trainees may accept modest meals when attending Industry-sponsored training and education regarding the use of medical devices.

5.3 Physician Services: Faculty may accept modest meals in connection with their performance of legitimate contractual services for Industry (e.g., consulting).

Under no circumstances may faculty or students/trainees accept money, entertainment, or other business courtesies in exchange for attending the meal. In addition, faculty and students/trainees may not allow Industry to pay for meals for their spouse, other immediate family member, or other guests who do not have a bona fide professional interest in attending the meal.

## **6. Industry-Sponsored Scholarships and Fellowships**

All offers of scholarships and fellowships from Industry must be submitted to the Feinberg Vice Dean for Regulatory Affairs for prior approval. In all such instances, the relevant department must have sole responsibility for determining the curriculum and selecting the recipient. There must be no *quid pro quo* for the acceptance of such funds.

Approval requests must be submitted to the Feinberg Vice Dean for Regulatory Affairs via the online Request for Approval Form available on the [Resources - Conflict of Interest and Professional Integrity](#) page of the [Office for Regulatory Affairs](#) website.

## **7. Use of Letterhead**

Any faculty member engaging in Outside Professional Activities must recognize that he/she is performing such activities as an individual and may not represent that he/she is acting on behalf of the University. The faculty member must take reasonable precautions to ensure that the outside employer or other recipient of services understands that the faculty member is engaging in the outside activity as a private citizen and not as an agent or spokesperson of the University.

Use of the official stationery of the University (letterhead stationery, letterhead envelopes), as well as use of the University as a business address may under no circumstances be used for outside

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nonprofessional activities, or Outside Professional Activities engaged in primarily for private purposes.

### **8. Relationships with the Investment Community**

Faculty should be aware of the risks associated with participating in expert advice panels hosted by the investment community, such as investment firms and hedge funds. Participating in an expert advice panel and potentially disclosing information that is not publicly available may put the faculty member at risk for insider trading liability. The safest course of action is to avoid participating in expert advice panels entirely. If one chooses to participate in expert advice panels, one can reduce the risk by ensuring that (i) the advice being sought is legitimately related to one's area of expertise, (ii) one's compensation reflects the fair market value; and (iii) the information one provides is publicly available.

### **9. Educational Grants and Donations**

Grants and donations from Industry must directly benefit patients or serve an educational purpose (e.g., a symposium with broad attendance). The provision of funding by Industry should never influence clinical decision-making, prescribing, or purchasing decisions, or the awarding of contracts. Accordingly, Feinberg will not accept funding that is offered in connection with the purchase or sale of goods or services.

In order to achieve the above, faculty (and their department or division) must comply with the following safeguards:

#### **For ACCME-accredited educational programs:**

9.1 Permitted support includes unrestricted funding for ACCME-accredited educational programs conducted by Feinberg to offset the cost of the CME program. The distribution of the funds must be in compliance with this Feinberg policy and Standard 3 of the ACCME's Standards for Commercial Support, including but not limited to:

- (a) All support must be given with full knowledge of the [Feinberg Office of CME](#);
- (b) Support must be used to pay all or part of the cost of the CME activity, including the services of the institution in the production and distribution of the activity; and,
- (c) The distribution of the funds must be outlined prior to the activity and the total amount of the grant is to be listed in the signed letter of agreement (LOA). The LOA must be signed by the Industry sponsor and the appropriate parties at Feinberg.

#### **For non-ACCME-accredited educational programs and other purposes:**

9.2 Only unrestricted educational grants or donations offered by Industry sponsors may be used for non-ACCME accredited educational programs if, *prior to acceptance*, they are

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reported to and approved by the Feinberg Vice Dean for Regulatory Affairs. Approval requests must be submitted to the Feinberg Vice Dean for Regulatory Affairs via the online Request for Approval Form, available on the [Resources - Conflict of Interest and Professional Integrity](#) page of the [Office for Regulatory Affairs](#) website.

- 9.3 The grant/donation must be memorialized in a written funding agreement with the Industry sponsor.
- 9.4 Industry sponsors may direct unrestricted grants to a specific department and indicate the therapeutic area of the program to be funded. Industry sponsors, however, are not permitted to specify or pre-approve program content or speakers. Prior to the start of the presentation, program organizers must announce the sponsoring organization(s), and all program speakers must disclose any financial relationships with the Industry sponsors providing the grant, and any other relevant financial relationships.
- 9.5 Materials advertising non-ACCME accredited educational programs must list the names of the sponsoring organization(s) and must be submitted to the Feinberg Vice Dean for Regulatory Affairs for approval prior to display or distribution. Program support by an Industry sponsor shall be disclosed to all recipients of program materials.
- 9.6 The department conducting the educational activity must independently develop a budget for any such project, and must ensure that donated funds are applied toward the applicable educational program.

#### **10. Access by Industry Representatives**

Unless required for training or treatment purposes, access by Industry representatives shall be restricted to non-patient care areas and should take place only by appointment or invitation of the faculty member. In general, involvement of students/trainees in such meetings should not occur. In addition, Feinberg faculty members and students/trainees must comply with the vendor access policies of our affiliated hospitals and practice groups.

Additional policies governing pharmaceutical samples, formulary and medical device evaluation as well as purchasing decisions and referrals are maintained by our affiliated hospitals and practice groups. Feinberg expects that these decisions will be made by the appropriate hospital committees rather than individuals.

## **F. REPORTING OF POTENTIAL VIOLATIONS OF THE FEINBERG POLICY**

### **1. How to Report a Potential Violation**

Reports of suspected, or potential, violations should be made to the [Office for Regulatory Affairs](#) or to NU in any of the following ways:

- 1.1 [Feinberg Office for Regulatory Affairs Reporting Methods](#):

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- (a) In person;
- (b) Via e-mail: [fsm-compliance@northwestern.edu](mailto:fsm-compliance@northwestern.edu);
- (c) Via phone: General Office Telephone 312-503-2855;
- (d) Via mail:

Interoffice mail addressed to:  
Feinberg Office for Regulatory Affairs  
c/o Director, Compliance  
Rubloff Building, 12<sup>th</sup> Floor Chicago Campus

US Mail addressed to:  
Northwestern University Feinberg School of Medicine  
Office for Regulatory Affairs  
c/o Director, Compliance  
420 E. Superior Street  
Arthur J. Rubloff Building, 12<sup>th</sup> Floor  
Chicago, IL 60611

or,

- (e) Via fax: 312-908-5502.

1.2 NU Reporting Method:  
NU Hot Line (EthicsPoint) 866-294-3545

In addition to the resources listed above, NU has selected EthicsPoint to provide faculty, staff, and students/trainees with a simple way to report activities that may involve misconduct or violations of NU policy. A report may be filed [here](#) or by dialing 866-294-3545. This service is not a substitute for, nor does it supersede, any existing reporting methods or protocols already in place at NU for reporting suspected problems or complaints. Instead, the EthicsPoint system provides an additional means of reporting such issues. Any suspected problems or complaints reported via EthicsPoint will be reviewed in accordance with current NU procedures, including those described in the Faculty, Staff, or Student Handbooks.

**2. Protection of a Reporting Employee**

NU policy prohibits the taking of retaliatory action against anyone for good faith reporting or inquiring about potential breaches of NU Policy or for seeking guidance on how to handle suspected breaches.