DISCLOSURE AND PROFESSIONAL INTEGRITY POLICY

Effective Date: November 1, 2012

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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 recently promulgated regulations from 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 faculty (including clinical associate faculty), contributed services faculty, health system clinician faculty, and regular-lecturer faculty) and students/trainees can advance public health and build relationships while maintaining objectivity, integrity, and public trust.

Additional policies governing pharmaceutical samples, as well as formulary and medical device evaluation and purchasing decisions 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 (including clinical associate 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
C. Definitions
D.1. Disclosure of Outside Professional Activities and Conflict of Commitment – Annual Disclosure
D.4. Disclosure of Outside Professional Activities and Conflict of Commitment – Conflict of Interest Disclosure for Industry-Sponsored Research
D.5. Disclosure of Outside Professional Activities and Conflict of Commitment – Faculty 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.2. Definitions – Industry Section
D.5. 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 Contractual Arrangements 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 – Educational Grants and Donations
E.8. 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.

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”). [definition is per the NU COI Policy]

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. An individual acting as a “project director or principal investigator and other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research” is an Investigator, or someone who assumes independent responsibility for portions of an Investigator’s proposed or funded project, which may include collaborators or consultants. [definition is per the NU COI Policy]

5. Outside Professional Activities. An outside activity is any paid or volunteer activity undertaken by a staff or faculty member 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. [definition is per the NU COI Policy]

D. DISCLOSURE OF OUTSIDE PROFESSIONAL ACTIVITIES AND CONFLICT OF COMMITMENT

1. Annual Disclosure
Feinberg administers an online Joint Affiliate Annual Disclosure Survey on behalf of itself and its affiliated hospitals and practice group. 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 as per this Feinberg Policy and the NU COI Policy. These disclosures include, but are not necessarily limited to:
Service on Boards of Directors
Ownership or Investment Interests
Compensation received from:
  o Academic/Other Professional Relationships
  o Industry Relationships
  o Royalty Payments and Inventor Share

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, and regular-lecturer faculty member’s private practice is also not included.

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

The process for review of faculty members’ 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
  o Consulting/Related Activities
  o Ownership or Investment Interests
  o Royalty Payments and Inventor Share
Medical Record Consultation/Expert Witness Testimony
Academic and Other Professional Activities

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 a Joint Affiliate Annual Disclosure Survey Administration Team. 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 Joint Affiliate Annual Disclosure Survey website is available and may be accessed annually as well as throughout the year for interim updates of 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 annual disclosure requirements may lead to disciplinary action, up to and including non-reappointment or recommendation to the NU Provost of termination of faculty appointment.

2. Transactional/Research-Related Disclosure
External research sponsors, and NU, seek to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research, including that supported by grants, cooperative agreements and contracts, will be free from bias resulting from Investigator financial Conflicts of Interest. In particular, the Public Health Service (“PHS”) has promulgated regulations on “Promoting Objectivity in Research.”¹ The NU COIR Policy is premised on the PHS regulations.

NU personnel who submit applications for funding to more than one external sponsor will be held to the most stringent standards of the various sponsors to which they apply. To the extent that such standards are more stringent than the NU COI Policy or the NU COIR Policy, the sponsor’s requirements will take precedence.

A list of disclosure requirements for various external sponsors can be found in the NU Research Sponsors Subject to Northwestern’s Research Conflict of Interest (COI) Disclosure Requirements document. NOTE: There is no de minimis threshold for Feinberg faculty member’s transactional/research-related disclosures.

2.1 To Whom Does the Transactional/Research-Related Disclosures Process Apply?
All faculty and staff must comply with the NU COI Policy and the NU COIR Policy. Any individual acting as a “project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research” is an Investigator and must satisfy the disclosure requirements of the NU COIR Policy.² The NU COIR Policy requires that: 1) all PHS-funded Investigators complete a training requirement via a training module available within the Faculty and Staff Information System (“FASIS Self-Service”); and, 2) all Investigators disclose any Significant Financial Interests (“SFI”) to NU by completing a survey within FASIS Self-Service, which allows for the electronic filing and management of these disclosures.³

¹ See 42 CFR Part 50, Subpart F and 45 CFR Part 94.
² See section 2 (To Whom Does this Policy Apply) of the NU COIR Policy for the full definition of “Investigator.”
³ See section 3 (Disclosure Requirements for Investigators) of the NU COIR Policy for a complete list of disclosure requirements for Investigators.
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2.2 When is Transactional Disclosure Required?
Individuals meeting the above criteria are required to make disclosures:

- At the proposal stage (the time of the research application);
- An update at the Just-In-Time (JIT) stage, or prior to receiving award;
- Annually, at the time of a non-competing progress report; and,
- Within 30 days of discovery or acquisition of a new SFI.

For PHS-funded Investigators, SFI also includes the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities (including that which is paid on behalf of the Investigator but not reimbursed to the Investigator so that the exact monetary value may not be readily available).

This disclosure requirement, however, does not apply to travel that is reimbursed or sponsored by a federal, state or local government agency, a qualifying institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

In addition, all faculty involved in human subjects research who are considered authorized personnel on a research project reviewed by the NU Institutional Review Board (“IRB”) must disclose to the IRB the existence of any potential Conflict of Interest that he/she or any member of the research team may have. Per IRB policy, these research-related transactional disclosures must include the existence of all financial interests of authorized personnel that are related to the research project.

3. 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. Annual disclosures may also be reviewed by a Joint Affiliate Disclosure Review Committee, comprised of compliance leadership from Feinberg and their affiliate practice group and hospitals.

Transactional research-related disclosures are reviewed by the NU Conflict of Interest Office (“NUCOI”) and the Feinberg Vice Dean for Regulatory Affairs and/or the Associate Dean for Research Operations. When necessary, disclosures may also be reviewed by the Feinberg Conflict of Interest Committee (“Feinberg COIC”).

In general, the IRB, the NU Office for Sponsored Research (“OSR”), the NUCOI, and the NU Conflict of Interest Oversight Committee (“COIOC”) work in partnership with the Feinberg Vice Dean for Regulatory Affairs to identify potential conflicts of interest related to the conduct of research and to ensure the integrity of the research program at NU. Potential conflicts of interest that are deemed to be significant or potentially significant during the annual survey process as well as through transactional research-related disclosure reporting will be referred to the Feinberg COIC. The Feinberg COIC, which is comprised of 15 to 20 active NU and Feinberg faculty and
staff, is chaired by the Feinberg Vice Dean for Regulatory Affairs who is responsible for identifying and approving committee membership. Additional information regarding the Feinberg COIC is available on the Feinberg COIC page of the Office for Regulatory Affairs website.

Per the NU COIR Policy, school-based Conflict of Interest committees such as the Feinberg COIC are responsible for establishing standards that provide a reasonable expectation that the design, conduct and reporting of research will be free from bias resulting from financial Conflicts of Interest. The Feinberg COIC is responsible for reviewing all Investigator SFIs that are disclosed annually as well as transactionally, and that have been referred to it by the Feinberg Vice Dean for Regulatory Affairs. The Feinberg COIC then considers the specific aims of the proposed or awarded project(s) and the appropriate disclosure thresholds to determine if the SFI rises to the level of a financial Conflict of Interest. If it does, the Feinberg COIC will work with the appropriate NU offices, including, but not limited to the IRB, the OSR, the NU COOI, and the COIOC, to develop a plan to manage, reduce, or eliminate the financial Conflict of Interest. The NU COOI and the COIOC will provide sponsors, as needed, and the public, upon request, with information regarding financial conflicts of interest for senior and key personnel per the NU COIR Policy.

In certain circumstances, if an actual conflict exists and a conflict management plan is not agreed upon by the faculty member, or if the Feinberg COIC concludes that the conflict cannot be managed but must be eliminated, the Feinberg COIC may recommend to the IRB, the OSR, the NU COOI, and/or the COIOC that the research not be permitted to continue due to the risk involved.

The IRBs are independent standing committees established under NU policy and federal regulations. Members of the IRB panels are appointed by the Director of the IRB Office with delegated authority from the Vice President for Research who, as described in the NU Human Subject Protection Program Policy Manual and under the terms of the Federalwide Assurance (an agreement between NU and the DHHS), is listed as the institutional signatory authority. As such, he/she assumes responsibility for ensuring NU is in compliance with the federal regulations regarding human subjects research. NU delegates this authority to the Vice President for Research because that office has sufficient authority and independence to implement and maintain a program of excellence in the NU Human Subject Protection Program.

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 Feinberg COIC. The Feinberg COIC will inform the IRB in each case of its decision. If a faculty member does not agree with the conflict management plan recommendations of the Feinberg COIC, the faculty member may follow the appeal process as outlined in the detailed process flows that are available on the Policy Links page of the Office for Regulatory Affairs website.
4. Conflict of Interest Disclosure for Industry-Sponsored Research
Per the NU COIR Policy, the Feinberg COIC must approve any proposed Industry-sponsored research study that may involve a Conflict of Interest. Furthermore, integrity must be protected by the establishment of an appropriate management plan in the following types of situations:

(a) A faculty member receives compensation from a research sponsor outside of and in addition to his/her research funding, which in the judgment of the Feinberg Vice Dean for Regulatory Affairs is a significant financial interest;

(b) A faculty member is involved in research involving his/her inventions/creations;

(c) A company licensed to use a faculty member's invention/creation is sponsoring the research; or,

(d) A faculty member's immediate family member has a financial interest in the outcome of the research.

NU will require disclosures from all Investigators who are proposing or participating in an Industry sponsored research project. However, the threshold for reporting SFIs for Industry based research projects will be at the zero dollar threshold. If the Feinberg COIC determines that the interest, whether financial or otherwise, represents a Financial Conflict of Interest ("FCOI"), the Feinberg COIC will work with the Investigator to develop a plan to manage, reduce, or eliminate the conflict.

5. Faculty Use of Students/Trainees in Outside Professional Activities
Student/trainee involvement in faculty enterprises may provide the potential for substantial benefits to the education and career development of the student/trainee. Such involvements need 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 Engagement in Faculty Enterprises Student-Faculty Agreement. 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

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, 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 Industry. This prohibition includes, but is not limited to:

- 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 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); 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.

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.

2. Physician 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 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 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 Contractual Arrangements. Students/trainees of Feinberg may not enter into contractual agreements 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 faculty member believes would advance the academic mission of his/her department or division; in which case, the faculty member shall explain the basis for this belief and receive approval from his/her Department Chair, Division Chief or Center/Institute Director and the Feinberg Vice Dean for Regulatory Affairs prior to attendance.

NOTE: Students/trainees may not attend non-ACCME Industry events described as continuing medical education.
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 for a third-party educational conference 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 of the conference, 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. 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.

(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.

If faculty wish to use an ACCME provider other than the Feinberg Office of Continuing Medical Education (“Feinberg Office of CME”) to sponsor an educational event, they may do so only after receiving the approval of the relevant Department Chair, or Center/Institute Director and the Feinberg Vice Dean for Regulatory Affairs.

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
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:

- 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.
- 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.
- 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.
- 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.
- 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 unless approved by the Feinberg Vice Dean for Regulatory Affairs. Except as provided below, 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.

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

- **Educational Conferences or Professional Society Meetings:** Faculty and students/trainees may attend meals and receptions provided by Industry in connection with an educational conference, training, or professional meeting only as permitted in this Feinberg Policy and with the requirements that:
  
  (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.

Meals, such as lunches, refreshments, and receptions that are included in the conference fee and available for all attendees are appropriate.

- **Medical Devices:** Faculty and students/trainees may attend modest meals and receptions when attending Industry-sponsored training and education regarding the use of medical devices.
- **Physician Services:** Faculty may attend modest meals and receptions 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 [Policy Links](#) page of the [Office for Regulatory Affairs](#) website.

### 7. 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:**
  - Permitted support includes funding for ACCME-accredited educational programs conducted by Feinberg to offset the cost of the CME program, such as catering, textbooks, educational materials, and outside speakers’ expenses. The distribution of the
funds must be in compliance with 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:

- All educational grants or donations offered by Industry sponsors may be used for non-ACCME accredited educational programs and other purposes if, prior to acceptance, they are 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 Policy Links page of the Office for Regulatory Affairs website.
- The grant/donation must be memorialized in a written funding agreement with the Industry sponsor.
- Industry sponsors may direct 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.
- 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.
- 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. Any funds remaining after completion of the educational program shall be used for educational purposes, or as otherwise required by the funding agreement. No donated funds may inure to the benefit of any Feinberg faculty, staff, or student/trainee.

8. 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. Involvement of students/trainees in such meetings should occur only for
educational purposes and always under the direct supervision of the faculty member. In addition, Feinberg faculty members and students/trainees must comply with the vendor access policies of our affiliated hospitals and practice groups.

F. REPORTING OF POTENTIAL MISCONDUCT OR VIOLATIONS OF FEINBERG POLICY

1. How to Report an Offense or Suspected Offense
Reports of suspected, potential, or known wrongdoing may be made to the Office for Regulatory Affairs or to NU in any of the following ways:

- **Feinberg Office for Regulatory Affairs Reporting Methods:**
  
  (a) In person;
  
  (b) Via e-mail: fsm-compliance@northwestern.edu;
  
  (c) Via phone: General Office Telephone 312-503-2855 (M-F; 8:30 AM - 5:30 PM);
  
  (d) Via mail:
    
    Interoffice mail addressed to:  
    Feinberg Office for Regulatory Affairs  
    c/o Director, Compliance  
    Rubloff Building, 12th 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, 12th Floor  
    Chicago, IL 60611  
    
    and,
  
  (e) Via fax: 312-908-5502.

- **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, students, and 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.