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Background and General Policy Information

Q: What is the purpose of the Feinberg Disclosure and Professional Integrity Policy (“Feinberg Policy“)?

A: The purpose of the Feinberg Policy is to foster an environment in which all Feinberg regular and research full-time and part-time faculty (including clinical associate faculty), contributed services
faculty, health system clinician faculty, regular-lecturer faculty, and students/trainees can advance public health and build relationships while maintaining objectivity, integrity, and public trust.

Q: How was the new Feinberg Policy developed and enacted?

A: The Feinberg Office for Regulatory Affairs led the effort to create the updated Feinberg Policy, benchmarking with other institutions, considering best practices, and soliciting input from Northwestern University (“NU”) faculty and staff.

Q: When did the updated Feinberg Policy take effect?

A: The updated Feinberg Policy went into effect on November 1, 2012, replacing the prior policy that was in effect from November 1, 2011 through October 31, 2012.

Q: Are there major changes in the new Feinberg Policy compared with the prior policy?

A: Yes. The updated Feinberg Policy was revised extensively from the 2011 version to incorporate changes to the NU Policy on Conflict of Interest and Conflict of Commitment (“NU COI Policy”) and the NU Policy on Conflict of Interest in Research (“NU COIR Policy”). A Summary of Changes document lists major policy revisions.

Q: How often will the Feinberg Policy be revised?

A: The Feinberg Policy will be reviewed every year and will be amended as necessary.

Q: How will the Feinberg Policy intersect with NU policies?

A: The Feinberg Policy is intended to be a supplement to the NU COI Policy and the NU COIR Policy. If Feinberg Policy is more stringent on any particular topic, the faculty member or student/trainee will be expected to comply with the Feinberg requirements.

Q: How will the Feinberg Policy intersect with the policies of the other Feinberg-affiliated institutions?

A: A faculty member or student/trainee is required to be in compliance with both the Feinberg Policy and any policy of an institution with which the faculty member or student/trainee is affiliated. If Feinberg Policy is more stringent on any particular topic, the faculty member or student/trainee will be expected to comply with the Feinberg requirements regardless of what the affiliated institution requires.
Application of the Feinberg Policy

Q: Who is subject to the Feinberg Policy?

A: The Feinberg Policy, in its entirety, applies to all Feinberg full-time and part-time (regular and research) faculty members. Only certain sections of the Feinberg Policy apply to contributed services faculty, health system clinician faculty, regular-lecturer faculty, and students/trainees, as shown below:

- Contributed Services Faculty, Health System Clinician Faculty, and Regular-Lecturer Faculty:
  - 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

- Students/Trainees: “Students/trainees” includes all students of NU while engaging in activities at Feinberg, as well as all housestaff members (residents and fellows) in McGaw Medical Center of Northwestern University training programs.
  - 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
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E.3. Professional Integrity – Attendance at Educational Programs
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E.8. Professional Integrity – Access by Industry Representatives
F. Reporting of Potential Misconduct or Violations of Feinberg Policy

General Disclosure and Conflict Management

Q: Who is required to annually disclose Outside Professional Activities?

A: The following Feinberg faculty members are required to disclose Outside Professional Activities annually:

- Full-Time Faculty (Regular and Research)
- Part-Time Faculty (Regular and Research)
- Contributed Services Faculty, Health System Clinician Faculty, and Regular-Lecturer Faculty
- Other Faculty (Adjunct, Emeritus, or Co-Terminus, if also a NMFF physician/consultant or NMH Medical Staff)

Q: How often will faculty need to report their financial interests to Feinberg under the Feinberg Policy?

A: Faculty members are required to report annually, through the electronic Joint Affiliate Annual Disclosure Survey, any relevant Outside Professional Activities and income earned during the previous calendar year (January-December). Additionally, faculty members are required to disclose any material changes to their financial interests between survey cycles. Additional information regarding the Joint Affiliate Annual Disclosure Survey is available on the Annual Disclosure Survey page of the Feinberg Office for Regulatory Affairs website.

Q: What financial interests must faculty disclose?

A: Feinberg faculty must disclose all Outside Professional Activities relevant to an individual’s role as a Feinberg faculty member. These include, but are not limited to:

- Service on Boards of Directors
- Ownership or Investment Interests
- Compensation received from:
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- Academic/Other Professional Relationships
- Industry Relationships
- Royalty Payments and Inventor Share

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

Q: Is there a minimum threshold for the dollar amount that must be disclosed?
A: No. There is no de minimis threshold for disclosure; all compensation – however small or large – must be reported.

Q: Is there any compensation that does not need to be disclosed?
A: The following types of compensation do not require disclosure:

- Compensation received from institutions or practice plans affiliated with NU and/or Feinberg
- Research grant amounts
- Research-based salary support related to a specific sponsored research project through NU or affiliated institutions
- Clinical practice income (e.g., income generated from patient care services)

Q: I am co-founder of a company, but I do not have any income from this relationship yet. Do I have to disclose it?
A: Yes. Any ownership or investment interest in a private company (including a start-up) must be disclosed if the company’s business is relevant to the individual’s role as a Feinberg faculty member.

Q: Do I have to disclose stock ownership?
A: Yes. Faculty members are required to disclose investor interest/ownership if they hold:

- Any ownership or investment interest in a private company (such as a start-up company); or,
- A greater than 5% ownership or investment interest in a publically traded company or mutual fund.
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Q: What information will be publically available on the Feinberg website (via the Faculty Profiles)?

A: We will list the following information (if applicable to you):

- 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
- Academic and Other Professional Activities

We will list only the names of the entities with which you have relationships, not the compensation amounts you have received from them.

Q: If I disclose a relationship on the Annual Disclosure Survey, does that mean I have a conflict of interest?

A: No. By disclosing your outside relationships, you are fulfilling the requirements of the Feinberg Policy. All disclosures are reviewed and a relationship is deemed a conflict of interest only when Feinberg Leadership or the Feinberg Conflict of Interest Committee (“Feinberg COIC”) makes that determination. Additional information regarding the Feinberg COIC is available on the Feinberg COIC page of the Feinberg Office for Regulatory Affairs website.

Q: Who will review the information that I disclose on the Annual Disclosure Survey?

A: For Feinberg faculty members who have multiple roles, a joint affiliate review process has been implemented, whereby disclosures are examined at three levels – by your division chief (when applicable), by your department chair, and by Feinberg and joint affiliate leadership (when applicable). Disclosures related to research may also be forwarded to the Feinberg COIC for further review and consideration.

Q: What happens if a Feinberg faculty member does not comply with the disclosure requirements?

A: Failure to comply with disclosure requirements may lead to disciplinary action, up to and including non-reappointment or recommendation to the NU Provost of termination of faculty appointment.
Transactional/Research-Related Disclosure

Q: If I am submitting a research grant, do I have additional disclosure duties?

A: 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.

Q: What are the disclosure requirements under the NU COIR Policy?

A: The NU COIR Policy requires that: 1) all Public Health Service (“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.

Q: When am I required to submit disclosures under the NU COIR Policy?

A: Individuals are required to make disclosure:

- 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.

Q: When do I need to enter compensation/reimbursement for travel?

A: For the annual disclosure purposes via the joint annual online disclosure survey, faculty must report the reimbursement of expenses or value of in-kind benefits for travel or meals as compensation.

For transactional research-related disclosure purposes via FASIS Self-Service, PHS-funded Investigators must report 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.
Q: If I am involved in human subjects research, do I have additional reporting duties?

A: Yes. If you are considered authorized personnel on a research project reviewed by the NU Institutional Review Board (“IRB”), you must disclose any potential conflict of interest that you or any member of your research team may have.

Disclosure Review and Conflict Management

Q: What is the Feinberg Conflict of Interest Committee (Feinberg COIC)?

A: The Feinberg COIC is the committee charged with reviewing and assessing potential research-related conflicts of interests. It is chaired by the Feinberg Vice Dean for Regulatory Affairs and is comprised of 15 to 20 active NU and Feinberg faculty and staff. Additional information regarding the COIC is available on the Feinberg COIC page of the Feinberg Office for Regulatory Affairs website.

Q: Which disclosures are reviewed by the Feinberg COIC?

A: Potential conflicts of interest that are deemed to be significant or potentially significant identified during the annual survey process as well as through transactional research-related disclosure reporting will be referred to the Feinberg COIC, which will determine whether an actual or potential significant conflict of interest exists.

Q: What happens if my financial interest is determined to be a significant conflict of interest?

A: If a significant conflict of interest is found, the Feinberg COIC will work in partnership with the appropriate NU offices, including, but not limited to the IRB, the NU Office for Sponsored Research (“OSR”), the NU Conflict of Interest Office (“NUCOI”), and the NU Conflict of Interest Oversight Committee (“COIOC”), to manage, reduce, or eliminate the research-related conflict of interest by creating and approving a conflict management plan. The NUCOI 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 NUCOI, and/or the COIOC that the research not be permitted to continue due to the risk involved.

Q: What if I don’t agree with the conflict management plan recommendations?

A: 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 Feinberg Office for Regulatory Affairs website.

Conflict of Interest Disclosure for Industry-Sponsored Research

Q: I am an Investigator on an Industry-sponsored research study. Am I required to follow the transactional research-related disclosure requirements?

A: Yes. Per the NU COIR Policy, all Investigators who are proposing or participating in an Industry sponsored research project must submit transactional research-related disclosures via FASIS Self-Service. The Feinberg COIC must approve any proposed Industry-sponsored research study that may involve a Conflict of Interest.

Q: What type of situations may require a management plan?

A: The following types of situations may require a conflict management plan:

- 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;
- A faculty member is involved in research involving his/her inventions/creations;
- A company licensed to use a faculty member's invention/creation is sponsoring the research; or,
- A faculty member’s immediate family member has a financial interest in the outcome of the research.

Faculty Use of Students/Trainees in Outside Professional Activities

Q: May I involve my students/trainees in my start-up company?

A: Yes. Per the NU COIR Policy, 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.

Gifts and Business Courtesies

Q: What is a gift or business courtesy under the Feinberg Policy?
A: 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.

Q: An Industry representative sent me a gift with a thank you note for trying a new product? Is this a permitted gift?

A: No. A faculty member may not accept gifts as a “thank you” for prescribing, purchasing or ordering products. The gift should be donated, disposed of, or, in the case that it is impractical to return it, shared with your department. Prior to sharing, all Industry identification must be removed. In addition, the Industry representative should be advised of our policy and asked not to send gifts in the future.

Q: How do I handle unsolicited gifts?

A: Do not accept the gift. If returning the gift is not feasible, then donate the gift or, in the case of a holiday food basket, share the gift with the department or practice area. Identifying information should be removed prior to sharing. Industry representatives and referral recipients should be asked not to send gifts in the future.

Q: My brother-in-law works for a drug company. Am I prohibited from accepting holiday gifts from him?

A: Gifts given by family members and by friends who are your friends independent of the business relationship (e.g., a college friend who happens to be a sales rep) are not prohibited. However, the types of gifts accepted should be appropriate to the relationship. A lavish gift from a distant relative would raise the question of whether the gift really arose from the family relationship, or was influenced by your status as a faculty member at Feinberg.

Q: I was given a gift certificate for attending a presentation on a new medical device. Is this appropriate?

A: No. Gifts – no matter how small – are not permitted.
Q: Do I have to get rid of pens, coffee mugs, posters, anatomical models, and similar items with Industry logos that my department received under the previous policy (when de minimis items were allowed)?

A: No. However, you may not accept any new items.

Q: As a Feinberg faculty member, can I accept new or revised textbooks from publishers requesting me to review the book for potential adoption, or as an instructor’s copy after the book has been adopted?

A: No. Accepting the textbooks as a free gift is prohibited.

Q: Is it appropriate for a medical device manufacturer, from whom my NMFF department or NMHC makes purchases, to provide a research grant to my Feinberg department?

A: The receipt of benefits in exchange for purchases raises possible ethical issues as well as legal issues under the Stark Law and Anti-Kickback Statute. Even if a purchase contract is silent as to the exchange or expressly states that the purchase is made independently of any other exchange between the parties, the facts and circumstances may still be problematic. If this situation arises, contact the Feinberg Office for Regulatory Affairs, NMFF, or NMHC attorneys as appropriate.

Physician Consulting, Advisory Boards, Speaking Engagements, and Similar Compensated Activities

Q: I provide consulting services on my own time. Why is this any of Feinberg's business?

A: The activities of faculty can reflect on Feinberg as well as the individual. The guidelines relating to consulting and other compensation arrangements are intended to protect both the individual faculty member and Feinberg from arrangements that could be viewed as improperly affecting medical research or clinical trials.

Q: Will Feinberg review and approve a faculty member’s proposed contract?

A: Faculty members enter into consulting agreements on an individual basis. Accordingly, you are responsible for negotiating the agreement’s terms and conditions at fair market value. However, the Feinberg Office for Regulatory Affairs is available to answer questions with respect to whether the agreement complies with the contracting guidelines set forth in this Policy. In addition, NU legal counsel should be consulted when a Northwestern affiliated institution may be affected by the arrangement (e.g., intellectual property rights).
Q: What kind of payment mechanisms are permissible? How do I know if the payment is ‘fair market value’?

A: As an initial matter, payment amounts or mechanisms need to be set in advance. Payment for services on an hourly basis is fine (as long as the amount paid per hour reflects fair market value). If payment is structured on this basis, it is very important that your services be documented (i.e. date, amount of time spent, description of activity) in order to justify the payment. We recognize that many arrangements may pay a per diem. This is fine as long the hours spent on the activity, when divided into the per diem, equals an hourly rate that reflects fair market value. Faculty members should avoid retainer arrangements where amounts are paid prior to and without regard to the performance of services. It is better to document time spent and submit this to the vendor for payment at rates that are not excessive. Fair market value can be established by looking at independent benchmarks (e.g., AAMC and MGMA compensation data).

Q: Am I covered by the insurance policy of Feinberg or other affiliated institutions when I do my outside consulting work?

A: No.

Q: How should I handle royalty payments?

A: When compensation is based on a royalty or similar arrangement, the payment amount should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence. Specifically, the payment amount:

- Must not be conditioned on a requirement that you or a Northwestern affiliated institution purchase, order, or recommend any product or medical technology, or a requirement to market the product or medical technology upon commercialization; and,
- Should exclude from the calculation of royalties the number of units purchased, used, or ordered by you, members of your practice, or any Northwestern affiliated institution.

Accordingly, for any agreement that does not comply, you should amend your royalty contract to exclude royalties for products purchased by any Northwestern affiliated institution. If doing so is not feasible, then contact the company to determine the amount of your royalties attributable to Northwestern affiliates purchases and reimburse the company that amount. Be sure to document everything and retain that documentation.

Q: Can faculty members participate in Industry-funded speakers’ bureaus?
A: Faculty members are not prohibited from participating in an Industry-sponsored speakers’ bureau, but are strongly discouraged from this activity. If a faculty member chooses to participate in a speakers’ bureau, the content and format of the presentation should be educational and must adhere to all FDA requirements.

Q: May a student/trainee enter into a contractual agreement with Industry?

A: No. Feinberg students/trainees 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 Vice Dean for Regulatory Affairs.

Attendance at Educational Programs

Q: Under what circumstances may I attend an Industry-funded medical education program?

A: Clinical faculty and student/trainees may only attend Industry-funded medical education programs if they fit one of the following categories:

- The program is an Accreditation Council for Continuing Medical Education (“ACCME”) accredited program;
- The program is sponsored by a Feinberg-affiliated institution or Feinberg and approved by the Feinberg Vice Dean for Regulatory Affairs;
- The program is part of a professional society meeting that follows ACCME standards; or,
- 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.

Q: I am a member of the scientific advisory board for a device company. A meeting of the scientific advisory board is scheduled for the day after a major medical conference in my specialty that I would like to attend. May I use the round trip ticket provided to attend the advisory board to attend the conference as well?

A: If the scientific advisory board meeting is a bona fide meeting of the advisory board, and the timing and location in connection with the conference make the advisory board meeting more convenient and likely to be attended by advisory board members, then the round trip ticket may
be used to attend the conference. However, advisory board meetings should not be scheduled before or after medical conferences as a pretext for funding attendance at the conference. In addition, conference registration fees, hotel expenses, and meals during the conference should not be paid by the advisory board sponsor.

**Q:** A medical device company proposes to pay for me to attend a medical conference and report back to the company on the proceedings. Is this appropriate?

**A:** No. This appears to be a pretext for paying for the expenses of attending a medical conference.

**Q:** There is a reception at a medical conference sponsored by a drug manufacturer that is open to spouses of attendees. Is this permitted?

**A:** The sponsor of a medical conference sets the rules for conference-related activities that may be supported by Industry. If the reception is not lavish, is subordinate to and does not interfere with the educational portion of the conference, and is open to all attendees, it is probably fine. However, a conference that includes extensive entertainment for attendees and spouses as opposed to focusing primarily on educational and scientific topics should be viewed with suspicion. Contact the Feinberg Office for Regulatory Affairs if you have any question about conference activities.

**Q:** I am a former or current leader of a third party not-for-profit professional organization and this organization has offered to pay my conference fee for their event. May I accept this offer?

**A:** Yes, you may accept the offer, but seek guidance from the Vice Dean for Regulatory Affairs prior to your acceptance.

**Training and Education Regarding the Use of Medical Devices**

**Q:** May I attend a medical device manufacturer-sponsored training held at a beach in Hawaii?

**A:** No. 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.

**Q:** Why am I prohibited from accepting payment from a manufacturer for attending a third party medical conference, but am allowed to do so to attend training on a manufacturer’s products?

**A:** There are similarities between the two types of programs. However, medical device companies have an obligation to ensure that their devices are used properly. Although training programs
Involving a manufacturer’s products may include general medical, scientific, and technical information, the primary focus is on the use of products. Such programs do not have independent value to physicians, but rather are provided to ensure that the products are used safely and effectively. Subsidizing attendance at third party educational events, on the other hand, potentially provides value to physicians and a Northwestern affiliated institution by reducing or eliminating the cost of Continuing Medical Education (CME) or the amount that otherwise would be spent to attend educational programs. Therefore, manufacturers should provide funding to the conference sponsor rather than individual attendees. Such funding may reduce the costs for all attendees, as opposed to being targeted to specific customers of the manufacturer.

Q: My Department is considering the purchase of a major piece of equipment. The equipment will be displayed and demonstrated at a medical conference. The manufacturer has offered to pay for two members of the Department to attend the conference to view the equipment. Is this permitted?

A: No. 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.

Q: While attending a training program on a new medical device, the manufacturer hosted a dinner reception for participants. May I attend the reception?

A: Yes. 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.

Meals

Q: A drug sales rep brings in lunch occasionally and provides information about the company’s products. Is this okay?

A: No. Sales representatives are no longer permitted to bring food on-site.

Q: What if the sales rep asked me to join him for lunch at a restaurant?

A: You can go to lunch, but the sales rep cannot pay for your meal. You would need to pay for your own meal.
Q: May I accept tickets to a charity benefit dinner or charity golf event, or funds to purchase tickets to a charity benefit or charity golf event, from Industry such as a drug company?

A: No. Industry may make a donation for such an event directly to the charity. If an Industry representative chooses not to use all of the tickets to the dinner or golf event, the Industry representative should let the charity choose persons to use the tickets.

Q: I can provide much more information about Feinberg programs to a potential referral source if I have his attention for several hours on the golf course than if I have him just for a lunch or dinner. Why is golf prohibited?

A: While it is possible to conduct legitimate business on the golf course, golf is inherently recreational, and providing recreational activities for referral sources could create the appearance that the purpose is to generate business.

**Industry-Sponsored Scholarships and Fellowships**

Q: How would my Department receive approval for an Industry-sponsored scholarship?

A: All offers of scholarships and fellowships from Industry must be submitted to the Feinberg Vice Dean for Regulatory Affairs for prior approval. 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 Feinberg Office for Regulatory Affairs website.

Q: My Department has been offered a fellowship from a drug company. The drug company wants to participate in the selection of the recipient. Is this permitted under the Feinberg Policy?

A: No. 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.

**Educational Grants and Donations**

Q: What are some examples of permitted educational grant and donations from Industry?

A: 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.
Q: I have received funding from Industry for an ACCME-accredited educational program. Are there any guidelines for the distribution of those funds?

A: Yes. 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:

- All support must be given with full knowledge of the Feinberg Office of CME;
- 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,
- 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.

Q: A pharmaceutical company has offered a non-ACCME accredited educational grant to my department. Does this need to be reported/approved?

A: Yes. All educational grants or donations offered by Industry must be reported to the Feinberg Office for Regulatory Affairs and approved by the Feinberg Vice Dean for Regulatory Affairs prior to acceptance. Submit Approval requests via the online Request for Approval Form available on the Policy Links page of the Feinberg Office for Regulatory Affairs website.

Q: I would like to use an educational grant from Industry for a non-ACCME accredited program. Is this permitted under the Feinberg Policy?

A: Educational grants or donations received from Industry sponsors may only be used for non-ACCME accredited programs if, prior to acceptance, they are reported to and approved by the Feinberg Vice Dean for Regulatory Affairs. The grant or donation must be memorialized in a written funding agreement with the Industry sponsor. Materials advertising such 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. Additionally, program speakers must announce the sponsoring organization(s) and any relationship or affiliation they have with the sponsor prior to the start of the presentation. Submit Approval requests via the online Request for Approval Form available on the Policy Links page of the Feinberg Office for Regulatory Affairs website.

Q: My Department is a very good customer of a certain drug company. Can I use information about our purchases in an application for a research grant?

A: No. Grants may not be solicited or accepted in return for or as a reward for purchasing or prescribing a vendor’s products. To avoid even the appearance of impropriety, discussions of grants should be completely separate from any discussions of purchasing. Many vendors have
separated their sales and marketing functions from their grant-making functions. You should report any vendor that attempts to link purchases and grants or donations to the Feinberg Office for Regulatory Affairs.

Access by Industry Representatives

Q: I understand that, as a Feinberg faculty member, I can no longer accept meals brought in by a pharmaceutical representative to be eaten during her presentation on new drugs. However, my staff works really hard and these occasional lunches are something they always enjoy. Is it really that big of a deal for the staff? They don’t make purchasing decisions.

A: Yes, it is a big deal. A faculty member should not do indirectly what he/she cannot do directly. This position also eliminates the appearance of impropriety.