# Office for Regulatory Affairs
## Compliance Program

April 16, 2012

### Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Compliance Program Overview</strong></td>
<td>2</td>
</tr>
<tr>
<td><strong>B. Seven Elements of Compliance</strong></td>
<td>2</td>
</tr>
<tr>
<td>1. Standards of Conduct/Policies and Procedures</td>
<td>3</td>
</tr>
<tr>
<td>2. Organizational Structure – Compliance Officer and Compliance Committee</td>
<td>3</td>
</tr>
<tr>
<td>3. Education</td>
<td>3</td>
</tr>
<tr>
<td>4. Monitoring and Auditing</td>
<td>3</td>
</tr>
<tr>
<td>5. Reporting and Investigating</td>
<td>3</td>
</tr>
<tr>
<td>6. Enforcement and Discipline</td>
<td>4</td>
</tr>
<tr>
<td>7. Response and Prevention</td>
<td>4</td>
</tr>
<tr>
<td><strong>C. Specific Description of the Feinberg Compliance Program</strong></td>
<td>4</td>
</tr>
<tr>
<td>1. Standards of Conduct/Policies and Procedures</td>
<td>4</td>
</tr>
<tr>
<td>2. Organizational Structure – Vice Dean for Regulatory Affairs / Compliance Officer</td>
<td>4</td>
</tr>
<tr>
<td>3. Education</td>
<td>6</td>
</tr>
<tr>
<td>4. Monitoring and Auditing</td>
<td>7</td>
</tr>
<tr>
<td>5. Reporting and Investigating – Reporting of Potential Misconduct or Violations of Feinberg Policy</td>
<td>9</td>
</tr>
<tr>
<td>6. Enforcement and Discipline</td>
<td>11</td>
</tr>
<tr>
<td><strong>8. Annual Compliance Work Plan</strong></td>
<td>12</td>
</tr>
<tr>
<td><strong>9. Joint Annual Disclosure Survey</strong></td>
<td>12</td>
</tr>
</tbody>
</table>
A. Compliance Program Overview
Northwestern University Feinberg School of Medicine (“Feinberg”) has been, and continues to be, committed to conducting its matters with integrity and in accordance with all federal, state, and local laws and ethical standards to which its operations are subject. It is Northwestern University (“NU”) policy to prevent and detect the occurrence of unlawful or unethical behavior (“non-compliant behavior”), including violations of the NU Standards for Business Conduct (http://www.northwestern.edu/auditing/how/standards.pdf), the Faculty Handbook (http://www.northwestern.edu/provost/policies/handbook/handbook.pdf), the Staff Handbook (http://www.northwestern.edu/hr/policies-forms/), the Human Resources Policies and Procedures Manual (http://www.northwestern.edu/hr/policies/), or this Compliance Program, to halt such non-compliant behavior as soon as reasonably possible after its discovery, to discipline personnel who engage in non-compliant behavior, including individuals responsible for the unreasonable failure to detect non-compliant behavior, and to implement any changes in policy and procedure necessary to prevent recurrences of non-compliant behavior.

In order to formalize compliance policies and efforts, Feinberg has adopted this Compliance Program (“Program”). This Program, as described herein, applies to all Feinberg faculty, staff, students, and trainees, including graduate medical education trainees supported through the McGaw Medical Center of Northwestern University. The Program also applies to our joint affiliates’ [Northwestern Memorial Healthcare (NMHC), Northwestern Medical Faculty Foundation (NMFF), The Children’s Memorial Medical Center (Children’s Memorial), and the Rehabilitation Institute of Chicago (RIC)] employees who provide services to Feinberg on NU premises, temporary agency personnel, and volunteers.

Recognizing that conducting this Program is an evolving process and is a part of the fabric of our organization, Feinberg will, from time to time, implement compliance-related policies and procedures, and may modify existing policies and procedures, consistent with its commitments to compliance. All such additional policies will be approved by the NU Vice President for Medical Affairs and Lewis Landsberg Dean of the Feinberg School of Medicine. Furthermore, the Office for Regulatory Affairs will be charged with assisting the departments within Feinberg Dean’s Administration (Academic Affairs, Budget and Finance, Communications, Development, Education, Information Technology, Operations, and Scientific Affairs) with the development, dissemination, training, and enforcement of their individual policies as well as with additional compliance-related activities.

This Program is not a statement of ideals; rather, it represents our commitment to an ethical way of conducting business and doing the right thing. This Program sets forth the means by which Feinberg’s compliance-related policies are to be implemented and monitored. It is imperative that all Feinberg personnel comply with this Program’s requirements and related policies, immediately report in good faith any suspected or actual non-compliant behavior, and assist NU and/or Feinberg in investigating any suspected or actual non-compliant behavior.

B. Seven Elements of Compliance
This Program has been developed voluntarily and with the intention of preventing and detecting non-compliant behavior. Feinberg’s Program is based on guidance from the Department of Health & Human Services (DHHS) Office of Inspector General (OIG). The OIG believes that every effective compliance program begins with a formal commitment to the seven elements of compliance, which are based on and expand upon the seven steps of the Federal Sentencing Guidelines. Accordingly, Feinberg’s Program shall provide for the following:
1. Standards of Conduct/Policies and Procedures

   Feinberg shall establish written compliance-related policies and procedures in connection with this Program to govern the activities of Feinberg personnel and encourage compliance while preventing and detecting non-compliant behavior.

2. Organizational Structure – Compliance Officer and Compliance Committee

   Feinberg shall establish an organizational structure that will facilitate an effective compliance and ethics program. This structure will include the following components:

   (a) The appointment of a Vice Dean for Regulatory Affairs and a Director of Compliance who shall be responsible for operating this Program;

   (b) A provision for the Vice Dean for Regulatory Affairs to report directly to the NU Vice President for Medical Affairs and Lewis Landsberg Dean of the Feinberg School of Medicine;

   (c) A provision for the Vice Dean for Regulatory Affairs to report, at minimum, annually to the NU Board of Trustees Medical Advisory Committee, and, more often as needed, to increase the Committee’s knowledge as to the content and operations of this Program and enable them to exercise reasonable oversight with respect to the implementation and effectiveness of this Program.

3. Education

   Feinberg shall take steps to communicate this Program, accompanying policies, and procedures to all Feinberg personnel through the publication and dissemination of materials. We will also require participation in compliance-related training programs. All communications and training will be appropriately tailored to the respective roles and responsibilities of the individuals.

4. Monitoring and Auditing

   Feinberg shall conduct monitoring and auditing efforts in key risk areas, including the monitoring of external professional relationships/conflicts of interest, HIPAA security/privacy/confidentiality, and research integrity.

   Additionally, Feinberg shall periodically assess the risk of non-compliant behavior and take appropriate steps to design, implement, or modify each requirement set forth above to reduce the risk of non-compliant behavior identified through this process.

5. Reporting and Investigating

   Feinberg shall take reasonable steps to ensure that this Program is followed, including establishing a reporting system whereby Feinberg personnel can report or seek guidance regarding potential or actual non-compliant behavior within NU without fear of retaliation. Feinberg will also create and maintain an issues tracking tool to document all compliance-related issues/concerns.
6. Enforcement and Discipline

Feinberg shall promote and consistently enforce appropriate incentives for individuals to perform in accordance with this Program, e.g., using compliance as an element in evaluating the performance of Feinberg staff, as well as using appropriate disciplinary mechanisms for individuals engaging in non-compliant behavior or for failing to take reasonable steps to prevent or detect non-compliant behavior.

7. Response and Prevention

Feinberg shall, in the case that non-compliant behavior is detected, take reasonable steps to respond appropriately and to prevent further offenses, including making any necessary modifications to this Program.

The above-listed components are more specifically described in the following sections with references to accompanying policies and procedures, as appropriate. When reading this document, be mindful that the Vice Dean for Regulatory Affairs and the Feinberg Director of Compliance may need to act through designated qualified individuals, utilizing NU and Feinberg staff and infrastructure to fulfill their responsibilities in enforcing this Program.

C. Specific Description of the Feinberg Compliance Program

1. Standards of Conduct/Policies and Procedures

Compliance policies and procedures are divided into two categories: (a) those policies and procedures directly related to the implementation of the components of this Program, and (b) those policies and procedures that are necessary to achieve compliance with various legal and ethical areas (e.g., privacy, security, research integrity, conflicts of interest, and professional integrity). All policies shall be approved by the NU Vice President for Medical Affairs and Lewis Landsberg Dean of the Feinberg School of Medicine prior to implementation. Procedures shall be brought to the NU Vice President for Medical Affairs and Lewis Landsberg Dean of the Feinberg School of Medicine’s attention, as appropriate. For purposes of this document, a “policy” is a general statement of Feinberg’s goal with respect to a particular subject matter. A “procedure” refers to the steps necessary to implement policies. The Director of Compliance will also create and maintain, in a readily accessible location (including the Feinberg Office for Regulatory Affairs website), a “resource binder” that contains this Program and related materials. All Feinberg faculty, staff, students, and trainees shall abide by Feinberg’s compliance policies and procedures, as applicable.

2. Organizational Structure – Vice Dean for Regulatory Affairs / Compliance Officer

The Vice Dean for Regulatory Affairs serves as the Chief Compliance Officer and reports to the NU Vice President for Medical Affairs and Lewis Landsberg Dean of the Feinberg School of Medicine. The Vice Dean is responsible for all oversight of this Program, including overseeing its implementation, and overseeing compliance with all applicable laws and ethical standards, this Program, and related policies. The Vice Dean for Regulatory Affairs is accountable to the NU Board of Trustees Medical Advisory Committee.
The Vice Dean for Regulatory Affairs, acting under the direction of NU counsel when appropriate, is empowered to investigate, evaluate and report facts, and to make recommendations to the NU Vice President for Medical Affairs and Lewis Landsberg Dean of the Feinberg School of Medicine and the NU Board of Trustees Medical Advisory Committee for possible responses or initiatives, including disciplinary actions for the non-compliant behavior of Feinberg faculty, staff, students, or trainees. The Vice Dean for Regulatory Affairs has the authority to review all documents and other information relevant to Feinberg’s compliance activities, including research records, patient records, billing records, and written arrangements with third parties. The designation of a Chief Compliance Officer, however, in no way diminishes the responsibility of other Feinberg personnel to comply with this Program and related policies.

The Vice Dean for Regulatory Affairs shall be responsible for coordinating the annual review and updating of this Program and related policies and procedures, keeping and maintaining all records necessary to protect the integrity of Feinberg’s compliance process, and confirming the effectiveness of this Program. Such review shall include documentation that faculty, staff, students, and trainees were adequately trained, that monitoring and auditing efforts occurred as stated, that disclosure records were maintained, that conflict management plan tracking occurred, and that issues documentation/tracking was completed as stated. The Vice Dean for Regulatory Affairs also shall be responsible for reporting to the NU Board of Trustees Medical Advisory Committee on at least an annual basis and for providing periodic updates as needed.

The Vice Dean for Regulatory Affairs heads the Office for Regulatory Affairs, which is comprised of a Director of Compliance, Compliance Consultant, and Compliance Analyst positions. These Feinberg staff perform not only Feinberg-specific compliance functions to meet the goals of this Program, but also perform work related to the administration and management of the Joint Annual Disclosure Survey process, on behalf of Feinberg, NMHC, NMFF, Children’s Memorial, and RIC. An organizational chart is provided below:

The organizational chart has been redacted. Please reference the Office for Regulatory Affairs Contact Us page for more information.
3. Education

It is critical to communicate this Program and its established policies and procedures to Feinberg faculty, staff, students, and trainees ("Feinberg personnel"). The Vice Dean for Regulatory Affairs is responsible for establishing procedures to ensure that Feinberg personnel are familiar with this Program and the policies and procedures that are applicable to their respective roles and responsibilities.

The Feinberg Office for Regulatory Affairs shall work with applicable departments at NU, and with leadership from our joint affiliate (NMHC, NMFF, Children’s Memorial, and RIC) compliance offices to ensure an effective education program is in place for Feinberg personnel.

(a) Who Should be Trained
Feinberg faculty, staff, students, and trainees shall be trained on applicable policies and procedures. Other individuals may be trained, as appropriate, depending upon the degree and type of interaction within Feinberg.

(b) Specific Training Procedures
Training procedures shall include, but are not necessarily limited to, the following:

- The Feinberg Director of Compliance is responsible for creating a compliance training program for Feinberg faculty, staff, students, and trainees. The Director is also responsible for creating and maintaining all training content, electronic training applications (which allow for customized training based on an individual’s role at Feinberg), and electronic training completion tracking and reporting.

- Beginning in FY 2013, upon initiation of an individual’s relationship with Feinberg, the individual shall be given a description of this Program and/or applicable policies and procedures. Faculty will receive this information in their orientation packet; staff will receive this information from NU Human Resources; students and trainees will receive this information either prior to or during their first onsite orientation.

- Also beginning in FY 2013, all current Feinberg faculty, staff, students, and trainees shall receive annual electronic compliance training. In addition, they shall receive, review, and acknowledge their understanding of this Program and the current policies and procedures in force under this Program (or a summary thereof) relevant to his or her position with Feinberg. The individual must electronically sign an acknowledgement stating that the individual has read, understands, and agrees to abide by this Program and other relevant policies and procedures.

- As new Program policies or procedures are adopted or existing policies are modified, Feinberg shall circulate the pertinent information to all Feinberg personnel who are affected by the policy or procedure and shall make it available on the Internet, as appropriate. This link will provide access to current online policies: [http://www.feinberg.northwestern.edu/compliance/links/](http://www.feinberg.northwestern.edu/compliance/links/).
- It is anticipated that the primary training method will involve a customized Internet-based program. Additional training methods may be used, as needed, and may include oral presentations, written materials, and videos.

In addition to formal training, Feinberg seeks to promote communications between Feinberg faculty, staff, students, and trainees regarding compliance-related matters and to create an environment that encourages and allows its personnel to seek and receive prompt guidance before engaging in conduct that may violate any law or policy.

4. Monitoring and Auditing

Feinberg is committed to ensuring that this Program is implemented and enforced through a system of periodic auditing and monitoring of its business activities. The Vice Dean for Regulatory Affairs is ultimately responsible for coordinating formal compliance audits of the Compliance Program, although independent internal or external auditors may also perform the audits. These audits are to detect adherence to this Program. The Vice Dean for Regulatory Affairs is responsible for investigating reports of suspected or actual non-compliant behavior. The results of the audit will be communicated to the NU Vice President for Medical Affairs and Lewis Landsberg Dean of the Feinberg School of Medicine and the NU Board of Trustees Medical Advisory Committee, who will determine whether any corrective action is necessary.

Additionally, compliance monitoring and auditing processes are divided into three categories: (a) those that deal with conflicts of interest related to external professional relationships, (b) those that are necessary to ensure compliance with various NU policies and federal regulations, including those related to HIPAA security/privacy/confidentiality, and (c) those that may help identify issues related to research integrity. All monitoring and auditing shall be approved by the Feinberg Vice Dean for Regulatory Affairs. RAT-STATS, a DHHS OIG-Office of Audit Services program, will be utilized to calculate audit populations of a statistically significant size, to perform random sampling, and to evaluate results. Potential audit plans shall be brought to the NU Vice President for Medical Affairs and Lewis Landsberg Dean of the Feinberg School of Medicine’s attention, as appropriate.

The above-listed monitoring and auditing categories are more specifically described below:

(a) External Professional Relationships

These relationships are monitored annually via the joint annual disclosure survey (explored in Section 9 below). Audits are also performed to determine the accuracy with which Feinberg faculty report their outside compensation related to external professional relationships. The audit procedure involves comparing self-disclosed compensation amounts, as captured by the joint annual disclosure survey, to the compensation amounts/physician payments that industry has begun publically disclosing in anticipation of the Sunshine Act requirements.

The Sunshine Act will require many drug, device, biological, and medical supply companies to publish transparency reports on payments to physicians and teaching hospitals. The law stipulates that these reports must be submitted with respect to the preceding calendar year and made available online. These provisions were signed into law with the passage of the Patient Protection
and Affordable Care Act (PPACA). The pertinent passage is Section 6002, entitled “Transparency Reports and Reporting of Physician Ownership or Investment Interests.” These online reports must be published no later than 09/30/2013, and on 06/30/20XX of each calendar year beginning thereafter. For more information about the Sunshine Act, reference the Compilation of PPACA prepared by the House Office of the Legislative Counsel.

The Joint Annual Disclosure Survey Administration Team will then be charged with following up with faculty members based on discrepancies found during the audit process, as well as compiling reports of audit results. These reports will be provided to NU Vice President for Medical Affairs and Lewis Landsberg Dean of the Feinberg School of Medicine’s attention, as appropriate.

(b) HIPAA

Maintaining the privacy, security, and integrity of data about our research participants, students, and staff is both an ethical and legal responsibility. As a result of the nature of clinical care and biomedical research, Feinberg faculty, staff, students, and trainees are likely to collect, use, manage, and be exposed to Protected Health Information (PHI) and Personally Identifiable Information (PII). As such, Feinberg has developed an additional policy, the Feinberg Information Security and Access Policy (“Information Security Policy”), which works in concert with NU-wide policies, regarding the appropriate use of electronic resources. The guidelines of the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act should be considered the minimum standard for handling PHI or PII. Additional information regarding the Information Security Policy is available on the Feinberg and Northwestern Policy website.

The Vice Dean for Regulatory Affairs and his office will work with Feinberg IT, as applicable, in order to ensure information security-related compliance at Feinberg. Various methods will be utilized to assess the handling of PHI and PII, such as audits of paper and electronic file security access and encryption.

(c) Research Integrity

The NU Office for Research Integrity is responsible for:

• Identifying compliance risks in our research practices and communicating those risks to the research community;
• Partnering with the research community in innovative and effective ways to minimize and manage research risks;
• Educating the research community with respect to appropriate business practices related to the conduct of research at NU; and,
• Monitoring and correcting non-compliance in accordance with University and federal guidelines.

The Vice Dean for Regulatory Affairs and his office will work with the NU Office for Research Integrity, as applicable, in order to ensure research-related compliance at Feinberg.

In addition to monitoring and auditing the above mentioned categories, Feinberg will also perform periodic risk assessments of areas identified as exhibiting non-compliant behavior. With the approval of the Vice
Dean for Regulatory Affairs and the NU Vice President for Medical Affairs and Lewis Lansberg Dean of the Feinberg School of Medicine’s attention, as appropriate, steps to address these risk areas and reduce non-compliant behavior through adjusting existing policies, creating additional policies, providing more education/training, etc., will then be taken.

5. Reporting and Investigating – Reporting of Potential Misconduct or Violations of Feinberg Policy

Feinberg is committed to the NU policy that all faculty, staff, students, and trainees have a responsibility to report any suspected or actual non-compliant behavior.

(a) How to Report an Offense or Suspected Offense

Reports of suspected, potential, or known wrongdoing may be made in a variety of ways to the Feinberg Office for Regulatory Affairs or to NU. The methods are listed below.

(i) Feinberg Office for Regulatory Affairs Reporting Methods

(a) Verbally or in person

(b) Via e-mail:

- Robert M. Rosa, MD, Vice Dean for Regulatory Affairs: rrosa@northwestern.edu
- Bridget B. Chamberlain, MBA, CHC, Director, Compliance: bridget-chamberlain@northwestern.edu
- Feinberg Compliance Office: fsm-compliance@northwestern.edu

(c) Via phone:

- Robert M. Rosa, MD, Vice Dean for Regulatory Affairs: (312) 908-8491; (M-F; 9:00 AM - 5:30 PM)
- Bridget B. Chamberlain, MBA, CHC, Director, Compliance: (312) 503-2855; (M-F; 9:00 AM - 5:30 PM)

(d) In writing:

- Interoffice mail:
  Feinberg Office for Regulatory Affairs
  c/o Director, Compliance
  Rubloff Building, 12th Floor
  Chicago Campus

- US Mail:
  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
(e) Via fax:
  - Attention: Director, Compliance - (312) 908-5502

(ii) Northwestern University Reporting Method
In addition to the resources listed above, NU has selected EthicsPoint to provide a simple way to report activities that may involve misconduct or violations of NU policy. One may file a report online or call the hot line.

Reports submitted via EthicsPoint will be handled as promptly and discreetly as possible, with facts made available only to those needed to investigate and resolve the matter. EthicsPoint and NU are committed to safeguarding the confidentiality of individuals who submit reports. Due to the nature of certain claims, NU may be limited with respect to potential responses to a report if the individual submitting the report does not wish to make his or her identity known.

All reports submitted through EthicsPoint will be carefully reviewed by Northwestern personnel. Upon submission, the individual will be assigned a Report Key and a private password. We encourage anyone making a report to return to this web site within 3-5 business days of filing a report. NU may have information on the report, or may require further information from the individual in order to proceed with an investigation.

This service is not a substitute for, nor does it supersede, any existing reporting methods or protocols already in place at Northwestern 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.

(a) Via phone:
  - Northwestern University Hot Line (EthicsPoint): (866) 294-3545

(b) Via online report:

(b) Protection of a Reporting Employee
NU policy prohibits the taking of retaliatory action against anyone for reporting or inquiring about potential breaches of NU policy or for seeking guidance on how to handle suspected breaches.

(c) Issues Tracking
Feinberg shall create and maintain an Issues Tracking Tool, for use by the Office for Regulatory compliance team in documenting all compliance-related issues/concerns.
6. Enforcement and Discipline

Adherence to the Program shall be a factor in Feinberg staff performance evaluations and compensation decisions. Currently, the NU Performance Excellence Annual Plan includes a “compliance” behavioral standard, which allows for an assessment of the employee’s honoring of the NU policies and regulatory requirements.

In addition, if an investigation or audit reveals that a Feinberg faculty member, staff member, student, or trainee engaged in non-compliant behavior, then that individual shall be required to attend training sessions and/or will be subject to appropriate disciplinary action. Feinberg shall document all reasons for disciplinary actions applied to Feinberg personnel for non-compliant behavior. The following factors may be taken into account in determining the appropriate disciplinary action to impose:

a) The nature of the non-compliant behavior and the ramifications of the non-compliant behavior for Feinberg;

b) The disciplinary action imposed for similar non-compliant behavior;

c) Any history of past non-compliant behavior;

d) Whether the non-compliant behavior was willful or unintentional;

e) Whether the individual was directly or indirectly involved in the non-compliant behavior;

f) Whether the non-compliant behavior represented an isolated occurrence or a pattern of conduct;

g) If the non-compliant behavior consisted of the failure to supervise another individual who violated this Program or its policies, the extent to which the circumstances reflect lack of diligence;

h) Whether the non-compliant behavior consisted of retaliation against another individual for reporting non-compliant behavior or cooperating with an investigation and the nature of such retaliation;

i) Whether the individual in question reported the violation; and,

j) The degree to which the individual cooperated with the investigation.

Feinberg may take a number of disciplinary actions against individuals who have violated any law or policy, ranging from a warning, up to and including termination and restitution of damages.

7. Response and Prevention

Anyone who reasonablysuspects or has actual evidence of non-compliant behavior, including a violation of this Program, is responsible for reporting that information in good faith. Reporting shall occur immediately through the means described above, in Section 5. Feinberg shall take reasonable steps to respond appropriately and to prevent further offenses, including making any necessary modifications to this Compliance Program. Feinberg faculty, staff, students, and trainees shall cooperate with any investigation – whether internal or external – and shall not intentionally or inadvertently destroy documents that might
be necessary for the implementation of this Program or that could lead to prosecution for obstruction of justice.

8. Annual Compliance Work Plan
The Feinberg Office for Regulatory Affairs has completed a compliance heat map, which addresses key elements of an effective compliance program versus potential compliance risks. The current compliance heat map document is shown below:

The Heat Map has been redacted.

In addition to creating and maintaining this document, the Feinberg Office for Regulatory Affairs completes both an office goals document and a compliance work plan, intended to outline the key goals of the office along with a specific plan of key compliance-related items that will be addressed during the current fiscal year. Both of these documents go hand-in-hand with the compliance heat map and are meant to not only continue to build and maintain a strong compliance program, but also to demonstrate compliance program effectiveness (per the seven elements).

9. Joint Annual Disclosure Survey
The joint annual disclosure survey (“Survey”) was developed to protect the fundamental mission of Feinberg - 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, Feinberg has adopted a Conflict of Interest and Professional Integrity Policy (“the Feinberg COI Policy”) that includes the implementation of the online Survey. This Survey is administered by Feinberg on behalf of the five (5) joint affiliates (Feinberg, NMHC, NMFF, Children’s Memorial, and RIC). Those individuals surveyed 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/commercial activities. These disclosures include, but are not necessarily limited to:

- Service on boards of directors
- Ownership or investment interests
- Compensation received from:
  - Academic/Other Professional Relationships
  - Industry Relationships
  - Royalty Payments and Inventor Share

In addition, individuals are required to disclose compensation for expert witness testimony, medical legal testimony, legal consulting, or other similar professional services. There is no de minimis threshold for disclosure. All external, professional activities related to the healthcare industry are to be reported, no matter the payment amounts.

The process for review of faculty members’ disclosures and implementation of appropriate conflict management plans, if applicable, is set forth via process flows (available online at http://www.feinberg.northwestern.edu/compliance/links/). Potential research-related conflicts of interest that are deemed to be significant or potentially significant will be referred to the Feinberg Conflict of Interest Committee (“COIC”). The COIC, which is comprised of 15 to 20 active NU and Feinberg faculty and staff, is chaired by the Vice Dean for Regulatory Affairs. The mission of the Feinberg COIC is to review and assess potential research-related conflicts of interest and determine if an actual conflict of interest exists. If the Feinberg COIC determines that an actual conflict exists, it will determine whether and how the conflict can be managed or minimized, or whether it must be eliminated and convey its conclusion to the principal investigator, as well as to the Institutional Review Board (“IRB”) and the Office for Sponsored Research (“OSR”). 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 and must be eliminated, the Feinberg COIC may recommend to the IRB and/or the OSR that the research not be permitted to continue due to the risk involved. Additional information regarding the COIC is available on the Office for Regulatory Affairs COIC website.

The overall survey process is managed by a joint affiliate survey team based within the Office for Regulatory Affairs. The Survey website link is: http://jointsurvey.feinberg.northwestern.edu, and may be accessed annually and throughout the year for updates.
Per this Program and the Feinberg COI Policy, 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 a faculty appointment.