



POLICY TITLE: Gifts and Interaction with Industry	SYSTEM POLICY AND PROCEDURE MANUAL
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Prepared by: Office of Corporate Compliance	Notations:

GENERAL STATEMENT of PURPOSE

The purpose of this policy is to provide parameters for appropriate decision-making regarding the acceptance or provision of business gratuities, gifts, activities and courtesies and other interactions between Individuals and Industry. All applicable Individuals shall receive training regarding potential conflicts of interest in interactions with Industry. Any questions as to whether a particular collaboration, interaction, relationship, gift, or social occasion would be appropriate in a specific circumstance should be directed to the Office of Corporate Compliance.

POLICY

It is the policy of Northwell Health that interactions with Industry should be conducted to avoid or minimize conflicts of interest. When conflicts of interest arise, they must be addressed appropriately as described in the Procedure section below.

Federal and State laws and the regulations promulgated thereunder (commonly referred to as the anti-kickback, Stark, and civil monetary penalty statutes and regulations) prohibit the acceptance of any item of value (remuneration) made directly or indirectly, in cash or in kind, that may induce or appear to induce the purchase, recommendation to purchase or referral of any kind of health care goods, services, or items reimbursed by a federal or state healthcare program such as Medicare and Medicaid. Consequently, the acceptance of any gifts or business courtesies from any third-parties with whom Northwell Health conducts business or who are seeking to do business with Northwell Health may implicate Federal and State prohibitions.

U.S. Centers for Medicare & Medicaid Services annually publish payments or transfers of value from drug and medical device companies made to certain healthcare providers and teaching hospitals (“Covered Recipients”) for consulting fees, meals, gifts, research and other forms of compensation or ownership interest on its Open Payments website www.cms.gov/openpayments. Open Payments is a national disclosure program that promotes a more financially transparent and accountable healthcare system. Therefore, Covered Recipients must annually review their information to ensure accuracy and dispute any payments reported in error.

In determining Industry and non-Industry conflicts of interest, Individuals shall also consult with policy #800.03 Conflict of Interest and Recusal and researchers shall also consult with policy #GR078 Review of External Consulting Relationships with Industry for Researchers.

SCOPE

This policy applies to all Northwell Health employees, as well as medical staff, volunteers, students, trainees, physician office staff, contractors, trustees and other persons performing work for or at Northwell Health; faculty and students of the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell or the Hofstra Northwell School of Nursing and Physician Assistant Studies conducting research on behalf of the Zucker School of Medicine on or at any Northwell Health facility.

DEFINITIONS

Conflicts of Commitment: A type of conflict of interest where the Individual's service to or activities with an outside organization interferes or has the appearance of interfering with the commitment, loyalty and time such Individual reasonably needs to devote in order to fully conduct their work at or for the hospital or entity within Northwell Health that employs such Individual.

Covered Recipients: Any physicians (excluding medical residents), physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and anesthesiologist assistants and certified nurse-midwives who are not employees of the applicable manufacturer that is reporting the payment; or teaching hospitals that receive payment for Medicare direct graduate medical education (GME), inpatient prospective payment system (IPPS) indirect medical education (IME), or psychiatric hospital IME programs during the last calendar year for which such information is available.

Gift: Anything of value an Individual receives from Industry for which the Individual has not paid or performed services in a manner that is routine in commercial transactions. Gifts include, but are not limited to: cash of any amount, gift certificates, loans, trade show/office trinkets or promotional items (e.g., pens, calculators, notepads, coffee mugs), flowers, food and beverage (e.g., box of chocolate, wine), entertainment or sports tickets, golf related items, stocks or other securities, or participation in stock offerings, Industry invitations to be their guests at charitable events sponsored by Northwell Health or other charitable organizations, raffle prizes, and use of Industry's vehicles or vacation facilities. Gifts also include any meals, food or beverage provided by Industry to Individuals on or off Northwell Health premises.

Individuals: All members of the Northwell Health workforce including, but not limited to, employees, medical staff, volunteers, students, physician office staff, and other persons performing work for or on behalf of Northwell Health.

Industry: Pharmaceutical, biotechnology, medical device and other healthcare related entities and their employees, representatives and other agents both on and off-premises owned or leased by Northwell Health, except where off-premises locations are specifically noted. This policy applies to conduct with Industry whether or not the particular Industry entity actually does business with Northwell Health.

Open Payments: A national disclosure program that promotes a more financially transparent and accountable healthcare system by making available to the public, the financial relationships between drug and medical device companies (Reporting Entities) and health care providers (Covered Recipients). Payments or transfers of value from Reporting Entities made to certain Covered Recipients for consulting fees, meals, gifts, research and other forms of compensation or ownership interest are submitted to the Centers for Medicare and Medicaid Services (CMS) and published through the Open Payments website www.cms.gov/openpayments.

Sample or Drug Sample: Free pharmaceutical products obtained from an Industry representative intended for clinical administration to a patient.

PROCEDURE

I. GIFTS FROM INDUSTRY

Gifts from Industry are prohibited regardless of any value because even gifts of a nominal value may be viewed to influence or potentially influence Individuals in the conduct of their duties or responsibilities. Gifts that are impermissible to Individuals are also impermissible when given to family members or guests of Individuals. Individuals must consciously and actively divorce clinical care decisions (including referrals, and diagnostic or therapeutic management) from any perceived or actual benefits accrued or expected from Industry including, but not limited to, research funding, scholarships for Continuing Medical Education (“CME”) attendance, and any compensation agreement.

Meals from Industry may be deemed to be gifts. Therefore, no industry-funded meals, food, or beverage of any nature or value are allowed, with two limited exceptions, as follows:

- a. Modest meals funded by Industry may be accepted by faculty providing compensated consulting services off-premises as an outside professional activity, and only in adherence with Northwell Health’s Conflict of Interest and Recusal policy (#800.03) and Review and Management of External Interests (COIs) in Research (Individual) policy (#GR065). Pursuant to policy #800.03, faculty must report the monetary value of meals funded by Industry, as the value of such meals may be reportable under the Open Payments program.
- b. Meals, food or beverage provided incidental to educational programs accredited by the Accreditation Council for Continuing Medical Education (ACCME), Joint Accreditation for Interprofessional Continuing Education, or other events that comply with the ACCME Standards for Integrity and Independence in Accredited Continuing Education, may be accepted. Further, such meals must be modest, provided for the purpose of promoting interaction and exchange between faculty and learners, and in all other respects must comply with the Northwell Health CME Policy on Commercial Support.

Gifts from Patients: Although this policy’s emphasis is on interactions with Industry, Individuals also are prohibited from accepting a personal, individual Gift of any kind from patients, former patients, their friends and relatives as individuals unless:

- a. The Gift is a modest token of appreciation rather than intended to influence behavior;
- b. The Gift does not involve cash or a cash equivalent such as a gift card; and
- c. The circumstances are such that refusal could be counterproductive to a patient

relationship.

Similar tokens of appreciation provided by a patient or the patient's family member to a facility department or office are also permissible. For any other gift, individuals must direct the donor to the relevant Northwell Health Foundation so that such Gifts can be made to the appropriate entity.

Social, Benevolence, Congratulatory Gifts, Business Courtesies: This policy does not apply to interactions between Individuals and Northwell Health and between Individuals and each other. Such interactions may involve a Gift as defined above. However, Individuals are reminded that Northwell Health's Business Courtesies to Potential Referral Sources policy (#800.10) addresses Business Courtesies, and certain Individuals have to report such Gifts for tracking purposes when provided to a potential referral source even when such Gifts are provided for social, benevolence, or congratulatory reasons.

Community Outreach and Education: Northwell Health may develop promotional items of nominal value that promote awareness of clinical programs consistent with Northwell Health's mission to provide community outreach and education.

Returning Unsolicited Gifts: If unsolicited Gifts arrive via the post office or private carrier, an Individual must inform the department head or administrator who will advise on the best method for returning the Gift.

II. COMPENSATION FROM INDUSTRY FOR CONSULTING SERVICES

Individuals who are invited by Industry to speak or to provide bona fide consulting services may accept reimbursement from Industry in the form of honoraria or compensation for the Individual's time spent and expenses incurred in the performance of such service if: 1) the services to be provided are specifically described in a written agreement that is signed by the Individual and Industry; 2) the compensation to be paid in exchange for such services is fixed prior to the services being performed, is fair market value for such services and also is described in the written agreement; and 3) prior to acceptance, the Individual has confirmed compliance with any relevant provision contained in a handbook, manual or contract that governs the terms and conditions of the Individual's employment, such as an employee handbook, faculty manual, or employment agreement.

In addition, the Individual must adhere to the following principles:

- a. Presentations or consultation engagements must be of scientific/academic merit and/or benefit Northwell Health;
- b. The activity does not involve an Industry-sponsored Speakers Bureau. Individuals are prohibited from participating in Industry-sponsored Speaker's Bureaus. Academic investigators are only permitted to present results of their research to peers and there is an opportunity for critical exchange;
- c. Presentations cannot be promotional in nature. Presentations must be purely educational, and the Industry must have no role in determining or approving presentation content;
- d. Individuals are prohibited from receiving compensation for listening to a sales pitch (e.g.,

detailing) by an Industry representative;

- e. Individuals must not receive any form of compensation from Industry for changing a patient's prescription or methodology of treatment;
- f. Individuals shall only accept fair market value compensation fees for specific, legitimate services provided by Individual and for work actually performed. Payment must be commensurate with time and effort and the terms of the arrangements and the services provided; and compensation must be set forth in advance and in writing. Any reimbursement for travel, lodging, and meal expenses must be reasonable and directly related to the engagement;
- g. Any agreement must not create any Conflict of Commitment;
- h. Acceptance of any Industry honoraria or agreement to perform consulting services is contingent on prior review and approval from an appropriate Administrative Director, Chairperson, or similar position. A Chairperson needs approval from the Chief Medical Officer and Researchers need approval from the Executive Vice President, or designee;
- i. The Individual must not perform any Industry-supported consultation or service agreement activity on non-Northwell Health work time unless approved by facility or department policy or by the Individual's manager;
- j. Compensation from Industry to Individuals must be disclosed in accordance with Northwell Health's Conflict of Interest and Recusal policy (#800.03) and Review and Management of External Interests (COIs) in Research (Individual) policy (#GR065) and Review of External Consulting Relationships with Industry for Researchers (#GR078) as applicable;
- k. Individuals with decision-making responsibilities in a procurement role must also follow Northwell Health's procurement policies; and
- l. In the event Northwell Health resources, such as work time, computers, and library, are involved in the consultation, Individuals must consult the policies of the site where such resources may be used. It is considered improper to use Northwell Health resources, especially computer resources, for non-Northwell Health purposes beyond incidental *de minimis* use.

III. ATTENDANCE AND/OR PARTICIPATION BY INDIVIDUALS IN INDUSTRY SPONSORED OR SUPPORTED PROFESSIONAL MEETINGS THAT ARE NOT SPONSORED BY NORTHWELL HEALTH

Education for Professionalism

This section applies to attendance and/or participation by Individuals at Industry sponsored or supported events that are not sponsored by Northwell Health. Clinicians are expected to participate in meetings of professional societies as part of their CME and professional obligations. Faculty and staff with special expertise may be invited to give lectures or otherwise participate in conferences and seminars in a variety of venues outside Northwell Health.

However, clinicians should be aware of the potential influence of Industry at these meetings. Industry support must never compromise academic independence or be presented such that one could infer that the purpose of the support of a meeting or conference was to induce or influence any favorable business action. Discretion must be employed in determining whether to attend, based on whether the event has a legitimate educational value.

Northwell Health permits attendance and participation by Individuals when an event is supported in part or in whole by Industry, and when certain requirements are met as described below.

Attendees

If an Individual is attending an education meeting or conference, as opposed to participating actively as discussed below (see “Participants”), the following criteria must be met:

- a. The event is offered by a professional society, academic institution or independent organization that affirmatively complies with the ACCME Standards or involves either training on the safe and effective use of a medical product and/or discusses non-promotional clinical educational information to further medical care;
- b. The Sponsor providing financial support of the event must be fully disclosed;
- c. The event, agenda and presentations include fair balance, and the content of the presentations are not determined by Industry unless FDA related or similar training is being provided or the information provided relates to either the safe and effective use of a medical product and/or non-promotional clinical education information to further medical care;
- d. No Gifts, compensation, travel, meals or lodging shall be accepted from Industry for attending an educational meeting or conference except for modest meals provided in compliance with the ACCME Standards (e.g., incidental to attendance of an off-site event);
- e. Presenters are required to disclose whether their presentation consists of their own studies and conclusions; and must confirm whether such studies and conclusions promote evidence based clinical care;
- f. Individuals must not accept any Gifts from Industry at such events;
- g. Industry support must not be displayed in presentation or education spaces; and
- h. The setting and cost of the event must be appropriate to its purpose.

Participants

Individuals who actively participate in meetings and conferences supported in part or in whole by Industry (e.g., giving a lecture, organizing the meeting, participating in FDA related training), must follow these additional requirements:

- a. The meeting or conference content is determined by the Individual and not the Industry Sponsor unless FDA or research related training is provided;

- b. The Individual must provide a fair and balanced assessment of therapeutic options and promote objective scientific and educational activities and discourse;
- c. The Individual is not required by an Industry Sponsor to accept advice or services concerning content, speakers, or other educational matters as a condition of the sponsor's contribution of funds or services;
- d. Individuals are prohibited from allowing their professional presentations of any kind, oral or written, to be ghostwritten by any party, Industry, or otherwise;
- e. The Individual explicitly describes all of the Individual's related financial interests (i.e., past, existing, or planned) to the audience or explicitly declares that the Individual has no related financial interests;
- f. The Individual states that the content reflects the Individual's views and not the views of Northwell Health unless approved by their Chair and the Department of Public Relations;
- g. The Individual may accept reasonable payment for travel, meals, lodging and honorarium of fair market value, but no reimbursement of family members or guests' travel expenses is allowed;
- h. Time spent in preparing and delivering the lectures does not impair the Individual's ability to fulfill Departmental responsibilities; and
- i. The use of the Northwell Health name at a non-Northwell Health event complies with policies regarding the use of Northwell Health's name (Use of Institutional Name policy (#500.02)).

In addition, participation involving speaking or similar responsibilities is subject to the requirements described in the "Compensation from Industry to Individuals" section of this Policy. Individuals uncertain about the appropriateness of a particular event or function should contact the Office of Corporate Compliance for guidance.

IV. INDUSTRY SUPPORT FOR RESEARCH RELATED ACTIVITIES

All Industry support for research related activities occurring throughout Northwell Health must be processed through or approved by the Northwell Health Grants Management Office ("GMO"), which resides in Research Administration at The Feinstein Institutes for Medical Research or the Northwell Health Foundation. Grants, awards and/or donations (collectively referred to as "Industry Support") from vendors to support research or education may be accepted by Northwell Health only if: (i) the Industry Support is accompanied with the vendor's certification that the Support is given to support Northwell Health research or education and is not intended to influence purchasing decisions or research outcomes; and (ii) it is approved by the academic Department Chair, and, if Northwell Health resources are used, by the Executive Director of the facility affected, and by the Executive Vice President, Research or designee with responsibility for the supported research or educational activity.

In addition, all policies and procedures promulgated by The Feinstein Institutes for Medical Research and the GMO relating to the submission, review, execution, and reporting of external funding for research must be followed. General grant policies may be located under the policies tab on the Intranet with detailed policies and procedures available on the GMO website: <http://www.feinsteininstitute.org/resources-for-investigators/grants-management-office-gmo/>.

V. INDUSTRY SUPPORT FOR NORTHWELL HEALTH SPONSORED CME AND OTHER NORTHWELL HEALTH SPONSORED EVENTS

Industry funding is not accepted for the support of accredited CME courses except in certain clearly defined circumstances aligning with restrictions set forth by ACCME Standards for Integrity and Independence in Accredited Continuing Education. Northwell Health's central departments managing CME oversee compliance with such ACCME Standards for Integrity and Independence in Accredited Continuing Education and have promulgated policies in adherence to them.

Individuals shall be aware of these policies: the Northwell Health Policy on the Content of CME; Policy on Commercial Support; and Policy on Collection of Financial Relationships and Resolution of Conflict of Interest. These policies are available from the CME Office.

Further, Individuals shall be aware of the Standards for Commercial Support established by the ACCME, on which these Northwell Health policies are based.

All educational events sponsored by Northwell Health that use Industry support must be compliant with the ACCME Standards, whether or not CME credit is awarded, unless FDA related or similar training is provided. Examples of permitted exceptions are set forth below:

- a. If the course would be prohibitively expensive or unaffordable to physicians without industry funding. Given its location in the Greater New York City area and large numbers of providers seeking CME education, Northwell Health frequently uses hotels as venues for CME programs. The associated costs, for example, of renting space at a major hotel in Manhattan make it necessary to accept some Industry funding in order to keep registration costs reasonable for attendees. Even in such exceptional cases, Northwell Health CME events must comply with all relevant policies and ACCME Standards for Commercial Support.
- b. Industry-supported educational events such as those described in example (a) above must separate education from promotion. Northwell Health ensures that activities do not promote the interests of product manufacturers through various safeguards, including but not limited to: separating commercial exhibits from the educational space at a hotel venue; and separating commercial advertising from educational content in an internet-based CME presentation.

Northwell Health conducts audits to assure compliance with these standards including those with respect to content validation and meals.

A complete description of the Standards of the ACCME to ensure independence in CME activities is available at:

<https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce>

In addition to the aforementioned ACCME Standards, educational events sponsored by Industry on Northwell Health's campus or a designated location should comply with the following provisions:

- a. Gifts of any type are not distributed to attendees or participants before, during, or after the meeting or lecture; and
- b. Funds from Industry to support the specific educational activity are provided to the Department or Program, but not to an individual faculty member.

Please contact the CME Office if you have any questions about CME or related Northwell Health event.

In addition to the above broad guidelines regarding the conduct of the event itself, the following provisions apply to the planning and organization of the event:

Solicitation: Industry Support may be solicited only for charitable, educational, academic or other appropriate purposes and must be approved by the Department Chair and/or the Foundation (if applicable). Such solicitation shall be made to all companies similar in nature to the one solicited, not just those doing business or potentially doing business with Northwell Health. Furthermore, such solicitation must clearly indicate that Industry Support is not a factor in vendor selection. Solicitation discussions must not involve Individuals with vendor or product recommendation roles or Industry sales and marketing personnel unless no other communication option is feasible.

Permitted Uses of Industry Support: Industry is permitted to support education and other Northwell Health projects and events, including but not limited to, research and fundraising projects that further the charitable mission of Northwell Health. Such Industry Support must be accompanied by a written certification from the appropriate Industry official that the support is provided to support education or a project or event that furthers the charitable mission of Northwell Health and that such Industry Support is not being provided to influence purchasing decisions or research outcomes.

Industry may direct its support to fully or partially fund an individual event, project or ongoing educational or charitable program of Northwell Health, but must indicate its request in its written certification. However, Northwell Health shall plan, operate and control all aspects of any such program in a manner consistent with the ACCME Standards (including, but not limited to, the provision of any food or beverages at such program, the selection of the program's content, faculty, attendees, educational methods and materials).

Product Training/Evaluation: Industry Support for a genuine, bona fide product education program or product symposium which by its nature may involve identification of an Industry name, logo or product is permitted if managed to eliminate or minimize the potential for advertising or other promotion.

Product Fairs or Similar Programs: Product fairs or similar promotional programs are allowed as long as these activities follow the ACCME Standards. Individuals who are faculty members must not be paid by Industry to do promotional speaking or to be on Industry-funded speakers' bureaus. Individuals who are in a position to recommend products for purchase shall review the above policy provisions regarding attendance and participation at such events. In addition,

such promotional events must meet the following two criteria: (a) the talk is not promotional in nature, but purely educational; and (b) Industry has no role in determining or approving presentation content.

Industry Financial Support: Industry Support for a Northwell Health event or project must not be made payable to an Individual but must be made payable to Northwell Health and sent to the applicable Northwell Health Finance Office, GMO, Foundation, or CME Office.

Management, Monitoring and Oversight of Industry Support: Developing a system that properly manages and monitors Industry Support can prevent the co-mingling of Industry Support with Northwell Health revenues and verify that Industry Support was used only for permitted uses. This system is crucial to preventing allegations that such Industry Support is an inappropriate form of support to Northwell Health.

Accordingly, all Industry Support funds must be allocated into Northwell Health's centralized accounts for accounting and oversight purposes. Checks received from Industry which by definition support temporarily restricted programmatic or research activities must be deposited into a separate Special Purpose Fund. The Northwell Health office responsible for securing the support (GMO or Foundation) will request the Special Purpose Fund, which will be set up by the Finance Department.

Further allocation to departmental accounts may be performed using the written certification from the Industry and/or the policies and procedures of the Finance Department. In addition, persons using Industry Support for a particular project or event must be able to document:

- a. the amount, source and date of the Industry Support received from Industry;
- b. the project or event receiving Industry Support;
- c. the amount of Industry Support applied to the project and event;
- d. the use of the Industry Support; and
- e. who determined the use of the Industry Support funds.

Users of Industry Support must seek guidance from Finance, the GMO and/or Foundations concerning the best method of monitoring and oversight that meets their particular situation.

Acknowledgement: Industry may be acknowledged for its donations or grants in a manner consistent with the ACCME standards.

VI. INDUSTRY SUPPORT FOR STUDENTS OR TRAINEES

Northwell Health facilities serve as training grounds for a variety of students and trainees. For the purposes of this section, the term "students" means persons enrolled in programs of study leading to a degree, and "trainee" refers to persons enrolled in post-graduate training programs. Industry support for trainees and students to attend conferences or trainings is prohibited.

Sponsoring Departments determine whether their budgets can allow for residents/fellows to attend their CME programs.

VII. ROYALTIES AND PAYMENTS FROM INDUSTRY AND EMPLOYEE-OWNED ENTERPRISES.

Individuals are advised that Northwell Health's Policy on Intellectual Property (#100.024) and Policy on Issuance of Northwell Licenses to Personally-Owned Entities (#100.026) and Policy on Technology Licensing and Distribution of Royalty Income (#100.027) govern patents and other intellectual property developed using Northwell Health resources. This policy is not intended to contradict or restrict the provisions of such policies.

Individuals involved in research or other activities using Northwell Health resources that give rise to intellectual property shall consult the Office of Intellectual Asset Management at the Feinstein Institutes for Medical Research.

In the event that an Individual has an agreement with Industry for royalties based on patents or other forms of intellectual property or for the receipt of other compensation (such as payments due to ownership interests) (each an "IP-Related Agreement"), the agreement must be structured (or re-structured, if necessary) to correspond to the policies and procedures of Northwell Health, as well as any applicable law.

The following requirements must be followed regarding structuring or restructuring of IP-Related Agreements:

- a. The IP-Related Agreement shall meet all contractual standards for consulting agreements described in Section II of this policy;
- b. The IP-Related Agreement shall be entered into only when the Individual has made, or is expected to make, a contribution that is scientifically novel, innovative and significant, and the Agreement shall provide sufficient detail to ascertain the contribution;
- c. The IP-Related Agreement shall not be conditioned on use or promotion by the Individual or Northwell Health of the contribution or of any other products or services of the other party or parties to the Agreement or their business affiliates; and
- d. To the extent practicable, all royalty-based or profit-sharing based payments to the Individual under the Agreement shall be calculated in a manner that excludes any sales of the product or service to Northwell Health by the other party or parties to the Agreement or their business affiliates unless there is a compelling clinical or business justification approved in writing in advance by the Office of Legal Affairs.

All arrangements described in this Section VII must be disclosed prior to employment in accordance with HR policies and annually thereafter to the Office of Corporate Compliance in accordance with Northwell Health's Conflict of Interest and Recusal policy (#800.03) and when involving research to the Office of Research Compliance in accordance with Northwell Health's Review and Management of External Interests (COIs) in Research (Individual) policy (#GR065).

Individuals also must submit to the Office of Corporate Compliance appropriate documentation to demonstrate compliance with this section of the policy.

VIII. DRUG SAMPLES TO INDIVIDUALS

“Samples” or “Drug Samples” means, for the purpose of this policy, free pharmaceutical products obtained from an Industry representative intended for administration to a patient. Many of Northwell Health facilities licensed under Article 28 of the New York Public Health Law prohibit or severely restrict the use of Drug Samples at their sites. In other areas, Individuals licensed to prescribe and dispense medications may accept Drug Samples from Industry for distribution to patients.

Distribution to persons other than patients carries the inference that such Drug Sample is a Gift and carries risk to an Individual’s professional reputation. Accordingly, Individuals who interact with Industry representatives concerning Drug Samples are strongly discouraged from accepting Drug Samples unless particular Samples pose significant benefits, are generally not used by the general population often, are usually needed quickly and whose benefits outweigh the regulatory, safety, security and other risks posed by such Samples.

For example, Individuals should refuse easily affordable or obtainable items that could be viewed as inappropriate (e.g., a widely used, over the counter product that one could find in a supermarket) but accept Samples for more expensive items that pose a problem for indigent clients or items that should reach the patient quickly after the patient encounter, and generally would not be viewed as inappropriate (e.g., an antibiotic).

Furthermore, to the extent that such Drug Samples are permitted, Individuals interacting with Industry representatives should cooperate with each other or with a Northwell Health site if feasible on managing Samples in a centralized manner that ensures security, timely access and tracks the recipients of Drug Samples. In the event such a centralized system is not feasible or interferes with access, Individuals should carefully consider alternative ways to manage Drug Samples in a manner that does not pose risk to their professional reputation.

Drug Samples shall never be sold and any drug sample shall not be used by Individuals for themselves or family members or anyone other than a patient in need of the particular Sample.

IX. INDUSTRY PRODUCT EVALUATIONS AND INDUSTRY SITE VISITS

Industry Product Evaluations

Industry may offer to place a new device or piece of equipment at Northwell Health on a trial basis. Such offers require Office of Procurement approval prior to delivery and the issuance of a no-charge Purchase Order that describes the item and the timeframe for the evaluation. Industry will be expected to deliver and retrieve the item within the designated time period.

The number of single use products (e.g., consumable or disposable products) provided at no charge must not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances. Multiple use products provided without transfer of title for evaluation purposes must be furnished only for a period of time that is reasonable under the circumstances to allow for an adequate evaluation.

Products used in a clinical research study are governed by the terms of the agreement or award and must be received pursuant to a requisition and Purchase Order and in accordance with Procurement’s Vendor Screening and Compliance policy (#300.16); and Procurement of Products and Services policy (#300.26). Individuals must not entertain or encourage such offers by Industry unless the device or equipment is necessary to further the clinical research study.

Individuals must not improperly influence the decision of the Office of Procurement in approving or disapproving an offer by Industry.

Industry Site Visits

Site visits for the evaluation of Industry products and/or services are sometimes appropriate parts of a purchasing decision. Also, site visits for either evaluating a technology or a product may be appropriate when evaluating a research or investment opportunity.

When such visits are necessary, they must be approved by the Department Chair and/or any applicable department leadership and paid with departmental funds. Industry support for such trips is prohibited.

X. SITE ACCESS BY INDUSTRY SALES AND MARKETING REPRESENTATIVES

The presence of Industry sales and marketing representatives at Northwell Health facilities presents operational issues of patient confidentiality, security, infection control, as well as a suggestion of an inappropriate relationship with Industry. The following requirements reduce the likelihood of an inappropriate presence of Industry:

Pharmaceutical Industry

- a. Northwell Health recognizes that its interactions with representatives of pharmaceutical manufacturers differ from its interactions with representatives of medical device and other Industry manufacturers.
- b. All pharmaceutical industry sales and marketing representatives' access is strictly prohibited to Northwell Health's premises, including but not limited to hospitals, outpatient clinics, pharmacies and the offices of employed physicians except as provided below.
- c. Pharmaceutical sales and marketing representatives with new or compelling data to present may request an appointment with Northwell Health Medication Education Committee through the Office of Northwell Health's Chief Pharmacy Officer/designee or through the Office of Procurement -- no other appointments or invitations are acceptable.
- d. Pharmaceutical Medical Liaisons also may be granted limited access only by prior appointment or invitation and such individuals must be credentialed by Northwell Health's vendor credentialing service described in policy "Company Representatives and/or Visitors in Patient Care Areas and NHPP Clinical Observers" (#100.22).

Medical Device and Other Non-Pharmaceutical Industry Manufacturers

- a. For representatives of medical device and other Industry manufacturers such as medical product manufacturers, access must be pursuant to an appointment or invitation related to the provision of medical care, such as providing technical support for the safe and effective use of medical devices or technologies, research studies, and authorized by the applicable faculty member or staff or otherwise permitted by "Company Representatives and/or Visitors in Patient Care Areas and NHPP Clinical Observers" (#100.22).

- b. Except as permitted by “Company Representatives and/or Visitors in Patient Care Areas and NHPP Clinical Observers” (#100.22), sales and marketing representatives of medical device and other Industry manufacturers are prohibited from interacting with patients (including observation) unless it has been approved by Northwell Health personnel and there has been prior disclosure to and consent by the patient and then only to provide in-service training, services or assistance on devices, equipment or other technologies.

Other Site Access Industry Requirements

All Industry representatives are also subject to policies of Northwell Health including, but not limited to, those concerning access and security, registering and credentialing an appropriate number of individual Industry representatives.

- a. All Industry representatives are to wear professional attire at all times. No “scrubs” are permitted unless provided by a Northwell Health employee for a specific purpose that requires “scrubs” or similar work-related attire (e.g., demonstration of product in a location requiring such attire). All attire provided by Northwell Health must be returned to the authorized Northwell Health employee immediately upon completion of the purpose requiring the attire (even if a repeated need for the attire is planned later in the day). Under no circumstances may Industry representatives leave the premises with any attire provided by Northwell Health.
- b. Involvement of students and trainees in such meetings shall occur only for educational purposes and under the supervision of a faculty member.
- c. Industry personnel are prohibited from distributing refreshments, meals, or Gifts during visits.
- d. Regarding access to appointments or invitations, all Industry sales and marketing representatives (pharmaceutical, medical device and other healthcare related entities and their employees, representatives and agents) are restricted to non-patient areas, non-public areas except when reasonable to access their appointment location or to provide in-service training or services on devices and other equipment as also described in “Company Representatives and/or Visitors in Patient Care Areas and NHPP Clinical Observers” policy (#100.22) and are expressly prohibited from loitering and conducting marketing and promotional activities with visitors, patients, employees, students and trainees en route to appointments.

XI. DISCLOSURE OF RELATIONSHIPS WITH INDUSTRY

Individuals are prohibited from publishing articles, scientific presentations or other related materials under their own names that are written in whole or in part by Industry or other individuals without proper attribution.

In scholarly publications, Individuals must disclose their related financial interests in accordance with the requirements of the International Committee of Medical Journal Editors (<http://www.icmje.org/>) or, if available, the requirements of the particular publication.

Individuals with supervisory responsibilities for students, trainees, residents or staff must ensure that any potential conflict of interest does not affect or appear to affect the supervision of any applicable Individual.

Any potential conflict of interest must be disclosed in accordance with the Northwell Health's Conflict of Interest and Recusal policy (#800.03) and Review and Management of External Interests (COIs) in Research (Individual) policy (#GR065). Individuals, including presenters, must comply with all Conflict of Interest disclosure policies, and reviews and management processes. To ensure transparency to learners, disclosure of any potential conflict of interest must include disclosure to trainees and audiences prior to or at the beginning of the CME activity to enable learners to take potential biases into consideration.

If disclosures of payments by Industry to physicians and teaching hospitals within Northwell Health are made from any regulatory agency (including but not limited to CMS Open Payments), it shall be the responsibility of the Individual or entity listed as the recipient, to review and if necessary, dispute such payment. The Office of Corporate Compliance shall serve as a resource for guidance.

Any applicable Individual with decision-making or a procurement role must also follow Northwell Health's Conflicts of Interest and Recusal policy (#800.03) and related policies. For example, Individuals may not participate in discussions or decisions on Northwell Health purchases of products or services from a company in which they have a financial interest. The same applies to purchase of products or services of a competitor of the company in which they have a financial interest.

XII. TRAINING, AUDITS, AND CURRICULUM

The Office of Corporate Compliance provides training on this policy on a regular basis. The Offices of Corporate Compliance and Research Compliance also conduct periodic audits to help ensure compliance with this policy. As part of the curriculum, the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell requires medical students to take a mandatory course which covers conflict of interest and physician relationship issues with Industry. These curricula are designed to develop the following two core competencies: (1) understanding the effects of Industry marketing on physician education and practice, and its relationship to medical professionalism; and (2) understanding the effects of industry influence on how the efficacy and safety of drugs and devices are demonstrated, regulated, and/or marketed.

XIII. ENFORCEMENT

Facility managers and Department Chairs shall be responsible for helping to enforce this policy. All violations must be reported to the Office of Corporate Compliance for appropriate resolution. Individuals found in violation of this policy may be subject to disciplinary action, up to and including sanctions for noncompliance. Exceptions to this policy can only be granted by the Chief Corporate Compliance Officer, or designee.

REFERENCES to REGULATIONS and/or OTHER RELATED POLICIES

- Administrative Policy #100.22, Company Representatives and/or Visitors in Patient Care Areas and NHPP Clinical Observers

- Administrative Policy #100.024 - Policy on Intellectual Property
- Administrative Policy #100.027 - Policy on Technology Licensing & Distribution of Royalty Income
- Administrative Policy #100.026 - Policy on the Issuance of Northwell Licenses to Personally-Owned Entities
- Administrative Policy #300.16 – Vendor Screening and Compliance
- Administrative Policy #300.26 – Procurement of Products and Services
- Administrative Policy #500.02 – Use of Institutional Name
- Northwell Health Policy #800.03 - Conflict of Interest and Recusal
- Northwell Health Policy #800.10 - Business Courtesies to Potential Referral Sources
- Northwell Health Policy #800.71 – Personal Investments in Northwell Health Interests
- Northwell Health Policy #GR065 – Review and Management of External Interests (COIs) in Research (Individual)
- Northwell Health Policy #GR078 – Review of External Consulting Relationships with Industry for Researchers
- Human Resources Policy – Part 5-4 Conflict of Interest, Gifts and Gratuities
- Northwell Health Policy on the Content of CME
- Northwell Health Policy on Commercial Support
- Northwell Health Policy on Collection of Financial Relationships and Resolution of Conflicts of Interest
- Northwell Health, “Policy on Conflicts of Interest and Interactions between Representatives of Certain Industries and members of the System Pharmacy and Therapeutics Committee for the Northwell Health” received courtesy of Office of Procurement.
- Hofstra University, Conflict of Interest and Commitment Policy and Addendum (last revised 3/2/10), available at https://www.hofstra.edu/about/policy/policy_cip.html.
- 42 CFR Part 403 Subpart I – Transparency Reports and Reporting of Physician Ownership or Investment Interests
- SUPPORT for Patients and Communities Act (Public Law No. 115-271)
- Outside Activity Guidance

CLINICAL REFERENCES/PROFESSIONAL SOCIETY GUIDELINES

- Standards for Integrity and Independence of Accredited Continuing Education (2020), available at: <https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce>
- Advanced Medical Technology Association (AdvaMed), “Code of Ethics on Interactions with Health Care Professionals,” (2021).
- Pharmaceutical Research and Manufacturers of America (PhRMA), “Code on Interactions with Health Care Professionals,” (June 30, 2020).
- Association of American Medical Colleges, “In the Interest of Patients: Recommendations for Physician Financial Relationships and Clinical Decision Making,” (June, 2010), available at www.aamc.org/publications.
- International Committee of Medical Journal Editors (ICMJE) Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals: Disclosure of Financial and Non-Financial Relationships and Activities, and Conflicts of Interest (December 2019), available at <http://www.icmje.org/recommendations/>.

- The Office of the Inspector General and the American Health Lawyers Association, “Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors.”

ATTACHMENTS

N/A

FORMS:

Outside Activity Form

<u>APPROVAL:</u>	
Northwell Health Policy Committee	10/28/2021
System PICG/Clinical Operations Committee	11/11/2021

Standardized Versioning History:

Approvals: * =Northwell Health Policy Committee; ** = PICG/Clinical Operations Committee; ☒ = Provisional; ❖ = Expedited

*06/27/13 **07/18/13;
 *02/26/15 **03/19/15
 *10/26/17 **11/17/17
 ❖12/19/19