North Shore – LIJ Health System, Inc.

POLICY TITLE: GIFTS AND INTERACTIONS WITH INDUSTRY POLICY	**ADMINISTRATIVE POLICY AND PROCEDURE MANUAL** **Section: Compliance and Ethics**
POLICY #: 800.04	**DEPARTMENT: Office of Corporate Compliance**
Approval Date: 11/17/11 **Effective Date:**	**Last Revised/Reviewed:** **11/11; 5/10; 10/05; 3/03**
Prepared by: Office of Corporate Compliance	**Superseded Policy(s)/#:** **N/A**

GENERAL STATEMENT of PURPOSE

Over the past few years, respected professional publications and associations have cited concerns over the extent, the potential for negative influence and damage to professional integrity, and the sheer diversity and complexity of collaborations between health care providers and Industry. Accordingly, numerous respected medical schools, academic medical centers, health care providers, and trade associations, whose members include Industry, have attempted to address these concerns by revising and updating their existing policies on gifts, conflicts of interest and similar matters to further regulate their interactions with Industry.

Federal and State laws and the regulations promulgated there under (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 health care program such as Medicare and Medicaid. Consequently, the acceptance of any gifts or business courtesies from any third-parties with whom the Health System conducts business or who are seeking to do business with the Health System may implicate Federal and State prohibitions.

In addition, the Health System adopted a Conflicts of Interest and Recusal policy (policy #800.03) with additional disclosure provisions to mitigate potential or actual conflicts of interest. Please be sure to consult this policy with regard to potential Industry or non-Industry conflicts of interest. Therefore, this policy is intended 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 or the Health System Foundation.

POLICY

It is the policy of the North Shore-LIJ Health System that interactions with Industry must 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.

SCOPE

This policy applies to all members of the North Shore – LIJ Health System workforce including, but not limited to, employees, medical staff, volunteers, students, physician office staff, and other persons performing work for or at North Shore – LIJ Health System.

DEFINITIONS

Individuals: All members of the North Shore – LIJ Health System workforce including, but not limited to, employees, medical staff, volunteers, students, physician office staff, and other persons performing work for or at North Shore – LIJ Health System.

Industry: Pharmaceutical, biotechnology, medical device and other health care related entities and their employees, representatives and other agents both on and off-premises owned or leased by the Health System, 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 the Health System.

Gift: A "Gift" means, for the purpose of this Policy, 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 tickets, golf related items, stocks or other securities, or participation in stock offerings, Industry invitations to be their guests at charitable events sponsored by the Health System or other charitable organizations, raffle prizes, and use of a Industry's vehicles or vacation facilities.

Gifts also include any food or beverage provided by Industry to Individuals on Health System premises except for Accreditation Council for Continuing Medical Education (ACCME) accredited programs or other events that comply with the ACCME Standards for Commercial Support. Individuals should use discretion in participating in any permissible Industry-sponsored meal off-site. Any meals should be modest in nature and provided incidental to attendance at an off-site event.

Sample or Drug Sample: means, for the purpose of this policy, free pharmaceutical products obtained from an Industry representative intended for administration to a patient.

PROCEDURE/GUIDELINES

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 also 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.

Patient Gifts: 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:

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

When feasible, Individuals should direct the donor to the relevant Health System Foundation so that such Gifts can be made to the appropriate entity. Similar tokens of appreciation provided by a patient or his or her family member to a facility department or office are also permissible.

Social, Benevolence, Congratulatory Gifts, Business Courtesies: This policy does not apply to interactions between Individuals and the Health System and between Individuals and each other. Such interactions may involve a Gift as defined above. However, Individuals are reminded that the Health System's 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: The Health System may develop promotional items of nominal value that promote awareness of clinical programs consistent with the Health System's mission to provide community outreach and education.

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

II. COMPENSATION FROM INDUSTRY FOR CONSULTING SERVICES

Individuals who are invited to speak or provide genuine consulting services can accept reimbursement from Industry in the form of honoraria or compensation for time and expenses, but must comply with the following requirements:

a. Presentations or consultation engagements must be of scientific/academic merit and/or benefit the Health System;

b. Individuals are prohibited from participating in Industry-sponsored Speaker's Bureaus unless academic investigators are presenting results of their research to peers and there is an opportunity for critical exchange;

c. Individuals are prohibited from receiving compensation for listening to a sales pitch (e.g., detailing) by an Industry representative;

d. Individuals must not receive any form of compensation for changing a patient's prescription;

e. Individuals must only accept fair market value compensation fees for specific, legitimate services provided by him or her and for work actually performed. Payment must be commensurate with time and effort and the terms of the arrangements, 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;

f. Acceptance of any Industry honoraria or consultation engagement is contingent on the prior approval from an appropriate Administrative Director, Chairperson, or similar position. A Chairperson needs approval from the Chief Medical Officer;

g. Any time spent on a consultation or service agreement must be performed on non-Health System work time unless approved by facility or department policy or by the Individual's manager;

h. Industry compensation must be disclosed in accordance with the Health System's conflicts of Interest and Recusal Policy #800.03 and the Health System's Conflicts of Interest in Research Policy #GR065, as applicable;

i. Any applicable Individuals with decision-making in a procurement role must also follow the Health System's procurement policies; and

j. In the event Health System 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 Health System resources, especially computer resources for non-Health System 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 THE HEALTH SYSTEM

Education for Professionalism

This section applies to attendance and/or participation by Individuals at Industry sponsored or supported events that are not sponsored by the Health System. 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 the Health System.

However, clinicians should be aware of the potential influence of Industry at these meetings. Industry support must never be 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.

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

Attendees

If an Individual is only attending an education meeting or conference, the following requirements must be followed.

- The event is offered by a professional society, academic institution or complies with the Accreditation Council for Continuing Medical Education (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;

- Financial support by Industry is fully disclosed at the meeting by the Sponsor;

- The event, agenda and presentations are not determined by Industry unless FDA related or similar training is being provided on either the safe and effective use of a medical product and/or non-promotional clinical education information to further medical care;

- No Gifts, compensation, travel, meals or lodging may 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);

- Presenters are required to disclose that their presentation consists of his or her own studies and conclusions and such studies and conclusions promote evidence based clinical care;

- Individuals must not accept any Gifts from Industry at such events;

- Industry support must not be displayed in presentation or education spaces; and

- 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:

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

- The Individual must provide a fair and balanced assessment of therapeutic options and promote objective scientific and educational activities and discourse;

- 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;

- Individuals are prohibited from allowing their professional presentations of any kind, oral or written, to be ghostwritten by any party, Industry, or otherwise;

- The Individual explicitly describes all of his or her related financial interests (i.e., past, existing, or planned) to the audience or explicitly declares that he or she has no related financial interests;

- The Individual states that the content reflects the Individual's views and not the views of the Health System unless approved by their Chair and the Department of Public Affairs;

- 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;

- Time spent in preparing and delivering the lectures does not impair the Individual's ability to fulfill Departmental responsibilities; and

- The use of the Health System name at a non-Health System event complies with Health System policies regarding the use of the Health System's name (Policy #500.02 – Use of Institutional Name).

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 advice.

IV. INDUSTRY SUPPORT FOR RESEARCH RELATED ACTIVITIES

All Industry support for research related activities occurring throughout the Health System must be processed through or approved by the Health System Office of Grants and Contracts, which resides in Research Administration at The Feinstein Institute for Medical Research or the Biomedical Research Alliance of New York (BRANY) or the Health System Foundation. Grants, awards and/or donations (collectively referred to as "Industry Support") from vendors to support research or education may be accepted by the Health System only if: (i) the Industry Support is accompanied with the vendor's certification that the Support is given to support Health System research or education and is not intended to influence purchasing decisions or research outcomes and (ii) it is approved by the Senior Vice President, Research or designee with responsibility for the supported research or educational activity.

In addition, all policies and procedures promulgated by The Feinstein Institute and the Office of Grants and Contracts 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 Healthport with detailed policies and procedures available on the Grants and Contracts website at www.nslij.com/ogc.

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

The Health System has centralized departments assigned to CME, which oversee all requests for Industry Support and receipt of funds for CME activity to ensure compliance with the ACCME Standards.

All Industry educational events sponsored by the Health System must be compliant with the ACCME Standards whether or not CME credit is awarded unless FDA related or similar training is provided. The Health System conducts audits to assure compliance with these standards including those with respect to content validation and meals.

Individuals should be aware of the Standards for Commercial Support established by the ACCME. A complete description of the Standards of the ACCME to ensure independence in CME activities is available at:

http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf.

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

- Gifts of any type are not distributed to attendees or participants before, during, or after the meeting or lecture; and

- 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 Office of Continuing Medical Education at (516) 465-3263 if you have any questions about CME or related Health System 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 the Health System. 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 Health System projects and events, including but not limited to, fundraising projects that further the charitable mission of the Health System. 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 the Health System 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 the Health System, but must indicate its request in its written certification. However, the Health System 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 or who are in a position to recommend products for purchase should review the above policy provisions regarding attendance and participation at such events.

Industry Financial Support: Industry Support for a Health System event or project must not be made payable to an Individual but must be made payable to the Health System and sent to the

applicable Health System Finance Office, Office of Sponsored Programs ("OSP"), Office of Grants and Contracts ("OGC"), Foundation, or Office of Continuing Medical Education.

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 Health System 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 the Health System.

Accordingly, all Industry Support funds must be allocated into Health System'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 Health System office responsible for securing the support (OGC, OSP, 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 and/or the Office of Sponsored Programs, Office of Grants and Contracts and the Foundation 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

Health System 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. The following requirements are designed to minimize potential influence by Industry on purchasing and referral decisions by facilities and faculty members:

- Scholarship and fellowship support by Industry is permitted, but must either be by a written grant with the Health System, through the Health System's Office of Sponsored Programs or Office of Grants and Contracts or the Health System Foundation, and placed in an account managed entirely by the Health System or be provided directly to a student or trainee from an independent medical association or similar entity in accordance with a local, regional or national competitive or recognition process;

- The Health System or the applicable educational affiliate must have complete control over the selection of recipients of scholarship or fellowship assistance;

- Industry grants to specific students or trainees are prohibited except for grants made: (a) as described above in which the Health System selects recipients; or (b) in accordance with a local, regional or national competitive or recognition process; and

- Per the "Gifts from Industry to Health System section," Gifts from Industry at such events is prohibited; and Industry support cannot be tied to the use of Industry products or any implicit or explicit *quid pro quo* (i.e., "no strings are attached").

VII. ROYALTIES, PATENTS AND OTHER INTELLECTUAL PROPERTY

Individuals are advised that Health System policy #GR017 governs patents and other intellectual property developed using Health System resources (Health System facilities, employees, and so forth). Policy GR017 does not allow arrangements between Individuals and Industry; rather, all such arrangements which involve use of Health System resources must be processed through the Feinstein Institute. This policy is not intended to contradict or restrict the provisions of #GR017. Individuals involving research, patent development, and other intellectual property arrangements using Health Systems resources should consult the Office of Technology Transfer at the Feinstein Institute. In the event that an Individual is involved in a project that does not involve Health System resources, such agreements between Individuals and Industry for royalties, patents, and other forms of intellectual property must be structured in a manner that assures that they are not being entered into in order to conceal impermissible compensation for business dealings (e.g., kickbacks). Accordingly, the following requirements must be followed:

- The Agreement shall meet contractual standards for consulting agreements (e.g., the agreement shall be written, fees disclosed annually, compensation at fair market value);

- The 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;

- The Agreement shall not be conditioned on use or promotion by the Individual or the Health System of the contribution or of any other products or services of the other party or parties to the Agreement or their business affiliates; and

- The Agreement shall be calculated in a manner that excludes reasonably foreseeable use by the Individual or the Health System of the contribution or of any other products or services of the other party or parties to the Agreement or their business affiliates.

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 the Health System 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 Health System 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 Evaluation Products

Industry may offer to place a new device or piece of equipment at the Health System 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.

Individuals must not entertain or encourage such offers by Industry unless the device or equipment is of genuine interest to the Health System. Individuals must not 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. 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 Health System 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 the inappropriate presence of Industry representatives and must be followed unless contraindicated by the Health System's applicable policy (see this policy's list of References) or by the applicable policy in effect at the particular Health System site:

- Industry sales and marketing representatives access is prohibited on the Health System's premises unless by appointment or invitation and must be credentialed by the Health System;

- Industry sales and marketing representatives 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 (refer to Policy #100.22, "Company Representatives in the Patient Care Area");

- Industry sales and marketing representatives are prohibited from interacting with patients (including observation) unless it has been approved by Health System 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;

- Involvement of students and trainees in such meetings should occur only for educational purposes and under the supervision of a faculty member; and

- Industry personnel are prohibited from distributing refreshments, meals, or Gifts during visits.

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

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 International Committee of Medical Journal Editors (http://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 Health System's Conflicts of Interest and Recusal Policy #800.03 and the Health System's Conflict of Interest in Research Policy #GR065.

Any applicable Individual with decision-making or a procurement role must also follow the Health System's Conflicts of Interest and Recusal Policy and related policies. For example, Individuals may not participate in discussions or decisions on Health System 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. ENFORCEMENT

Hospital and site 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.

Exceptions to this policy can only be granted by the Chief Corporate Compliance Officer.

REFERENCES to REGULATIONS and/or OTHER RELATED POLICIES

Administrative Policy #100.22 "Company Representatives in the Patient Care Area"

Administrative Policy #500.02 – Use of Institutional Name

Corporate Compliance Policy #800.03 - Conflicts of Interest and Recusal Policy

Corporate Compliance Policy #800.04 - Gifts, Gratuities, and Business Courtesies

Corporate Compliance Policy #800.10 - Business Courtesies to Potential Referral Sources

Research Policy #GR065 - Conflicts of Interest in Research Policy

Research Policy #GR017 – Intellectual Property

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Liaison Committee on Medical Education, "Functions and Structure of a Medical School, Standards for Accreditation of Medical Education Programs Leading to the M.D. Degree," June, 2008.

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Association of American Medical Colleges, "Industry Funding of Medical Education: Report of an AAMC Task Force," (June, 2008), available at www.aamc.org/publications.

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Stanford University, Stanford Industry Interactions Policy, effective October 1, 2006, available at http://med.stanford.edu/coi/siip/ and Stanford Policy on Compliance with the ACCME Standards for Commercial Support and Stanford Commercial Support of CME Activities FAQs, September 22, 2008, updated December 2, 2008, available at http://med.stanford/edu.

Yale University, Yale University Policy on Conflict of Interest and Conflict of Commitment, Revised, May, 2004, available at www.yale.edu/provost/html/coi.html.

Bernard Lo and Marilyn J. Field, Conflict of Interest in Medical Research, Education, and Practice, Institute of Medicine (2009), summary available on the Internet at http://www.nap.edu/catalog/12598.html.

Partners Healthcare, Partners Commission on Interactions with Industry (April, 2009), available at: http://www.partners.org/documents/CommissionReport_PartnersHealthCare2009.pdf.

Sen. Special Comm. On Aging, *Commercial Sponsorship of Continuing Medical Education: Testimony of Lewis Morris, Chief Counsel, Office of the Inspector General, Department of Health and Human Services* (July 29, 2009), available at: **http://www.oig.hhs.gov/testimony/docs/2009/07292009_oig_testimony.pdf.**

CLINICAL REFERENCES

APPROVAL: To Include Committee Name / Approval Date	
System P&P Committee	10/13/09; 11/8/11
System PICG Committee	10/22/09; 11/17/11