



Innovation Management and Conflict of Interest Program

Policy VI – Conflicts of Interest in Clinical Practice

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Printed copies are for reference only. Please refer to the electronic copy for the latest version.

Purpose

To assure professional and commercial integrity in all matters, our Organization maintains a program that identifies and addresses conflicts of interest in clinical practice.

Policy Statement

Having Relationships with Non-Cleveland Clinic (CC) Entities While Engaging in Clinical Practice

This policy applies to Target Group Professional [Staff](#), advanced practice providers, pharmacists, residents and fellows who provide healthcare to our Organization's patients (Healthcare Providers) [See also the [Conflicts of Interest in Research Policy](#)]. A Healthcare Provider may deliver outside lectures or external activities related to their [Institutional Responsibilities](#) for which he or she receives [Honoraria and/or Consulting Compensation](#) from a [Non-CC Entity](#), as long as the Healthcare Provider complies with applicable policies referenced herein and the provisions in the Policy Implementation section below. Under the policies, when the compensation—which may be direct or indirect, financial or otherwise—is received by an [Immediate Family](#) Member or an entity controlled by the Healthcare Provider or [Immediate Family](#) Member, it is treated as compensation to the Healthcare Provider. Target Group Healthcare Providers may also engage in activities related to the commercialization of intellectual property, as long as the Healthcare Provider complies with this and other policies related to conflicts of interest and commercialization of intellectual property. The intent of this policy is to ensure that the Healthcare Provider's primary concern is promoting the best interests of their patients.

The Innovation Management and Conflict of Interest (IM&COI) Program will review all potential [Conflicts of Interest](#) in clinical practice and may require certain actions, such as disclosure to patients, limits on the relationship with the [Non-CC Entity](#) or adoption of a Conflict Management Plan, to ensure, to the extent possible, that the clinical activity is free from bias that may result from the Financial Interest. In its evaluation of [Conflicts of Interest](#) in Clinical Practice, the IM&COI Program will strive not to interfere with clinical practice. Any required actions will not limit the clinical activities that Target Group Healthcare Providers believe to be in the best interests of his/her patients; rather, the IM&COI Program will make efforts to manage the relationship or Financial Interest in the [Non-CC Entity](#).

Definitions

Target Group - herein defined as Cleveland Clinic United States locations- Includes the main campus, Avon, Euclid, Fairview, Hillcrest, Lutheran, Marymount, Medina, Mercy, South Pointe, Children's Hospital for Rehabilitation, Weston Hospital, Coral Springs Ambulatory Surgery Center, Martin North Hospital, Martin South Hospital, Tradition Hospital, and all Family Health Centers, Physician practice sites, Nevada practice sites, Emergency Departments, Express Care Centers, Urgent Care Centers and Ambulatory Surgical Centers reporting to these facilities.

Policy Implementation

Receipt of Gifts by Healthcare Providers from Non-CC Entities

In general, Target Group Healthcare Providers and their [Immediate Family](#) Members may not accept gifts from [Non-CC Entities](#). Gifts include any transfer of value (financial or otherwise) provided by a [Non-CC Entity](#) to a Target Group Healthcare Provider that is not for services rendered or is not for goods received or that is in excess of fair market value and includes, but is not limited to, compensation for attendance at a conference, goods, cash, gift cards, meals*, travel and event tickets. Accepting items of minimal value, such as flashlights, pens and notepads, is discouraged but not prohibited.

*Exception for Meals: It is permissible to accept meals that are off-site of our Organization's facilities paid for by [Non-CC Entities](#) if these meals are modest, infrequent from a single provider and served during or in conjunction with medical education, healthcare information exchange, biomedical research discussions, or discussions of data relevant to clinical practice. [Subject to [Policy VII on Conflicts of Interest in Education](#)]

The Institution will only accept philanthropic gifts from Non-CC Entities if made through the Philanthropy Institute in accordance with its policies.

[See also [Policy VII Conflicts of Interest in Education](#) for other limitations regarding gifts]

Distribution of Non-CC Entity-Derived Materials Containing Information Directed at Patients as Part of Clinical Practice or Patient Education

Educational materials directed at patients that are developed by [Non-CC Entities](#) for use in patient care may only be made available following approval by a Target Group Professional [Staff](#) physician. If the Target Group Professional [Staff](#) physician has financial interests of any kind related to the company in question, he/she may not participate in the determination. In that case, the Institute Chair in collaboration with the Department Chair in that Institute must decide whether the materials will be made available. The decision will be based on the best interests of patients and the limitation of inappropriate [Non-Cleveland Clinic \(CC\) Entity](#) influence. Educational items with [Non-CC Entity](#) logos are discouraged.

[See also the [Pharmaceutical Representative Policy](#). Also, the receipt of educational materials directed at providers is subject to the requirements of [Policy VII Conflicts of Interest in Education](#).]

Having Financial Interests in a Non-CC Entity (stock, stock options, rights to royalties or other commercialization revenues, receiving consulting, speaking or other fees) While Using the Entity's Product in Treating Patients

All Target Group Healthcare Providers who have a Financial Interest in a [Non-CC Entity](#) making drugs or devices being used by or at the direction of the Healthcare Provider to diagnose or treat patients, whether the use is on-label or off-label, must receive approval from the IM&COI Program unless the total of the annual fees for services, annual royalties, and the approximate market value of the holdings over the prior 12 months are below \$20,000 from a single [Non-CC Entity](#) and the stock holdings are less than five percent of the [Non-CC Entity](#) (excluding stock held in a diversified mutual fund). The IM&COI Program may require elimination or a reduction of the Financial Interest or devise a Conflict Management Plan, which may include disclosure to patients, to ensure, to the extent possible, that clinical practice is free from bias that may result from the Financial Interest. Certain types of relationships will be publicly disclosed

via public webpages, brochures or other means generally accessible to our Organization's patients.

[For relationships with [Non-CC Entities](#) related to the use of experimental devices and drugs, see the conflict of interest policies that pertain to research, i.e., [Conflict of Interest Policies III](#) and [IV](#).]

Donating to Charities Part or All of Honoraria or Consulting Compensation, Royalties and Other Revenues from Commercialization Received from Non-CC Entities

The potential of a [Significant Financial Interest](#) ("SFI") to create a [Conflict of Interest](#), or in research, either a Conflict of Interest or PHS-Reportable Financial Conflict of Interest, is not eliminated by donating [Honoraria or Consulting Compensation](#) or [Royalties and Other Revenues from Commercialization](#) received from [Non-CC Entities](#) to a charity designated by the individual with the [SFI](#). The only exception to this provision is where the individual with the [SFI](#) donates the [Honoraria or Consulting Compensation](#), or [Royalties and Other Revenues from Commercialization](#) to the Cleveland Clinic Innovators' Charitable Fund.

No Royalty Payments or other Commercialization Revenues for use at our Organization of Products Commercialized by our Organization or developed by our Organization's Employees

See [Policy III Conflicts of Interest in Research](#) for restrictions on the receipt of royalty revenues from products used, sold or purchased by our Organization. There is no restriction on the receipt of royalty payments by our Organization or its Healthcare Providers for the purchase and use of products at locations other than our Organization.

Patient Referrals to a Physician, Entity or Practice with which there is a Potentially Conflicting Relationship with the Referring Healthcare Provider

A conflict of interest between the recipient of a referral and the referring Target Group Healthcare Provider occurs when the referring Healthcare Provider or member of his or her [Immediate Family](#) could benefit financially from the referral. If the referring Healthcare Provider is personally compensated by a [Non-CC Entity](#) or the referring Healthcare Provider or member of his/her [Immediate Family](#) owns any part of a company to which he/she is referring a patient, approval must be obtained from the IM&COI Program and the Law Department. In all cases, prior to referral, approval must be obtained from the referring Healthcare Provider's Department Chair and his/her Institute Chair (or equivalent) must be notified. He/she must also disclose the relationship to the patient being referred and any reasonable alternatives shall be made clear.

The restrictions herein do not apply when a Healthcare Provider is referring a patient to a sub-unit of our Organization (e.g., but not limited to, when a physician is referring a patient to radiology, but not to a specific radiologist and the physician's spouse works in radiology). It is emphasized that all referrals of patients be made based on the best interest of the patient.

Distribution of Prescription or Over-the-Counter Samples to Patients

Our Organization has a policy containing specific restrictions regarding drug samples. [See [Pharmaceutical Sales Representatives Policy](#), [where adopted](#)]

Site Access to our Organization by Pharmaceutical, Diagnostic and Medical Device Non-CC Entity Representatives

The Target Group has a policy pertaining to site access by Pharmaceutical Representatives. This policy hereby extends the limitations contained in the Department of Pharmacy Policy to include all [Non-CC Entity](#) representatives. [See [Department of Pharmacy Policy, Pharmaceutical Representative Guidelines](#), and the [Conflict of Interest Procedure for Vendors, where adopted](#)].

The IM&COI Program may grant exceptions where the [Non-CC Entity](#) representative visit is of direct benefit to a patient currently being treated.

Ghostwriting

Target Group [Staff](#), Residents, Fellows and Employees are prohibited from allowing their professional presentations, oral or written, to be ghost-written by other(s). Ghostwriting encompasses instances in which a person who qualifies for authorship is not acknowledged or listed as an author on a publication and instances in which a person who does not qualify for authorship is named as an author on a publication. All persons designated as authors must qualify for authorship. [Qualifications for authorship must be in accordance with the Guidelines for Manuscripts and Books and Commercial Publication, included in the [Major Policies for the Professional Staff \(Yellow Book\), where adopted](#)]

Oversight and Responsibility

The Innovation Management and Conflict of Interest Program is responsible to review, revise, update, and operationalize this policy to maintain compliance with regulatory or other requirements.

It is the responsibility of each hospital, institute, department and discipline to implement the policy and to draft and operationalize related procedures to the policy if applicable.