

Innovation Management and Conflict of Interest Program

Policy V - Consulting and Other Fee for Service Activities

Target Group:		Original Date of Issue:	Version
Cleveland Clinic United States Locations		September 6, 2006	4
Approved by:	Date Last Approved/Reviewed:	Prepared by:	Effective Date
Board of Directors	5/25/2021	Cory Anand, J.D., Director, Conflict of Interest	5/25/2021
Avon Hospital:		Euclid Hospital:	
Board approval date: 5/25/2021		Board approval date: 5/25/2021	
Effective Date: 5/25/2021		Effective Date: 5/25/2021	
Fairview Hospital:		Hillcrest Hospital:	
Board approval date: 5/25/2021		Board approval date: 5/25/2021	
Effective Date: 5/25/2021		Effective Date: 5/25/2021	
Lutheran Hospital:		Marymount Hospital:	
Board approval date: 5/25/2021		Board approval date: 5/25/2021	
Effective Date: 5/25/2021		Effective Date: 5/25/2021	
Marymount Hospital:		South Pointe Hospital:	
Board approval date: 5/25/2021		Board approval date: 5/25/2021	
Effective Date: 5/25/2021		Effective Date: 5/25/2021	
CCCHR:		Weston, Florida:	
MEC approval date: 5/25/2021		MEC approval date: 5/25/2021	
Board approval date: 5/25/2021		Board approval date: 5/25/2021	
Effective Date: 5/25/2021		Effective Date: 5/25/2021	
Mercy Hospital:		Coral Springs, FL ASC/FHC:	
Board approval date: 11/17/2021		MEC/CSOC approval date:5/25/2021	
Effective Date: 5/9/2022		Board approval date:5/25/2021	
		Effective Date:5/25/2021	

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 related to consulting and other fee for service activities.

Policy Statement

Engaging in External Activities

A Target Group Professional <u>Staff</u> member ("Staff"), Resident, Fellow or Employee may use his or her professional competence to engage in external activities for which he or she receives compensation from a source other than our Organization, as long as they comply with the provisions in the Policy Implementation section below. This policy also applies when the compensation—which may be direct or indirect, financial or otherwise—is received by an <u>Immediate Family</u> member (or an entity controlled or directed by the Target Group <u>Staff</u> member, <u>Resident, Fellow, Employee</u> or <u>family member</u>). Examples of compensation include, but are not limited to, honoraria, consulting fees, lecture fees, stock or stock options, royalties, and "in kind" compensation. This policy does not address Employment type relationships (which are generally prohibited for members of the Target Group Professional Staff) but must be disclosed, as applicable.*

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

Pre-Approval of Honoraria and Consulting Compensation by Members of the Target Group Professional Staff

Before engaging in any external activities that require one's professional competence to earn the types of compensation described in (5) below, a Target Group <u>Staff</u> member must receive notice of approval from the Law Department. Department chairs (or other immediate superiors) will be made aware of all external activities; any disputes will be resolved by the Target Group <u>Staff</u> member's Institute chair.**

• NO DISCLOSURE REQUIRED for These Types of Compensation

(1) Compensation for income from seminars, lectures, teaching engagements or service on advisory committees or review panels sponsored by United States government agencies; United States institutions of higher education as defined at 20 U.S.C. 1001(a);United

States academic teaching hospitals; or medical centers, or research institutes that are affiliated with an institution of higher education, unless they are described below in (2), (3), or (4). Note that disclosure **is required** for affiliations with foreign government agencies; foreign institutions of higher education; foreign academic teaching hospitals and foreign medical centers or research institutes that are affiliated with an institution of higher education.

DISCLOSURE but not PRE-APPROVAL REQUIRED for These Types of Compensation (see EXAMPLES below)

- (2) <u>Honoraria or compensation of \$10,000 or less during a 12-month period</u> from any single source for Consulting related to <u>Institutional Responsibilities</u> not described in (1) above
- (3) <u>Any</u> direct or indirect compensation of \$10,000 or less during a 12-month period from any single source for services related to <u>Institutional Responsibilities</u>, including any compensation from pharmaceutical, device and biotechnology companies, spin-off and venture partner companies of our Organization, medical education companies, medical publishing groups, corporate donors, other entities that provide healthcare, and major vendors
- (4) Honoraria or fees for Speaking at ACCME accredited events not described in (1) above

• For Target Group Professional Staff, PRE-APPROVAL OF WRITTEN AGREEMENT by the Law Department is required for:

(5) Any compensation over \$10,000, or involving receipt of equity in a private company, from (2) or (3) above during a 12-month period from any single source

• EXAMPLES of External Activities Requiring Disclosure and Pre-Approval, as applicable

- Advising a pharmaceutical company about emerging technology
- Serving on a scientific advisory board or other Pharma Advisory Committee
- Speaking at a conference in return for payments from pharmaceutical companies (or their affiliates), including payments from medical education companies indirectly supported by industry

Retaining Compensation; *Exceptions*: Expert Witnesses Fees

Compensation for external activities may be retained by Target Group <u>Staff</u> members, Residents, Fellows and Employees personally, except that any compensation paid for serving as an expert witness, for giving a deposition or for acting as a consultant in a legal proceeding - even "after hours" service - must be remitted to our Organization and credited to operating income.

Prohibited External Activities

Target Group Staff members, Residents, Fellows and Employees must not:

• Engage in advising or otherwise contracting with Financial Investment Firms or firms that broker for Financial Investment Firms. (Private equity or venture capital firms that evaluate new technologies for their own benefit are not considered Financial Investment

- Firms. Consulting for them involves the institutional disclosure and pre-approval process required when consulting for entities other than Financial Investment Firms.)
- Engage in activities in direct conflict with our Organization's mission or business position in a matter
- Engage in purely marketing activities for the pharmaceutical/ biotechnology health industry, e.g., speaking or writing papers favoring a company's products or disfavoring its competitors' products
- Receive compensation from a <u>Non-Cleveland Clinic (CC) Entity</u> for performing any of their professional activities at our Organization, e.g., for allowing observation or shadowing during surgery
- Incur a Conflict Of Interest, including a <u>Significant Financial Interest</u> or <u>Institutional Financial Interest</u> in research, without disclosure to the IM&COI Program. Note that Target Group Professional Staff members shall not receive compensation for clinical activities performed outside the scope of their employment at our Organization, unless approved by the Chief of Staff

Bona Fide Services; Fair Value; Keeping Records

Compensation from Non-CC Entities must never be an inducement or reward for the referral or generation of health care business. External consulting activities must be bona fide services that are documented in writing by a letter or written agreement, and the compensation must be for a demonstrably fair market value. Detailed records of Honoraria and Consulting Compensation must be kept by Target Group Staff members and Employees for five (5) years and given to the Innovation Management and Conflict of Interest Program upon request. When entering into arrangements to engage in external activities, Target Group Staff members, Residents, Fellows and Employees are encouraged to use personal legal counsel to ensure his/her own protection and compliance with applicable fraud and abuse laws. The Law Department does not assess the legal risk to the individual.

No Liability Protection Afforded by Our Organization

Our Organization does not provide liability protection (insurance) for any external activities, except for Law Department-approved pro bono and expert witness activities when the compensation, if any, is remitted to our Organization.

Right to Prohibit External Activity

The Organization reserves the right to prohibit any external activity if doing so is in the best interest of the Organization, regardless of the nature of the activity or the Target Group Staff member's, Resident's, Fellow's or Employee's compliance with this policy.

^{*} See Policy II regarding disclosure requirements.

^{**} Department chairs must acknowledge all external activities of Target Group Staff members. Institute chairs must acknowledge all external activities of department heads and resolve any disputes between Target Group Staff members and their department heads. The Chief of Staff must acknowledge all external activities of Institute chairs. The Board of Trustees or its designated committees must approve external activities of Officers, e.g., President and Chief of Staff.

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.