



## Innovation Management and Conflict of Interest Program

### Policy III – Conflicts of Interest in Research

<b>Target Group:</b> Cleveland Clinic United States Locations		<b>Original Date of Issue:</b> 2007	<b>Version</b> 3
<b>Approved by:</b> Board of Directors	<b>Date Last Approved/Reviewed:</b> 5/25/2021	<b>Prepared by:</b> Cory Anand, J.D., Director, Conflict of Interest	<b>Effective Date</b> 5/25/2021
<b>Avon Hospital:</b> Board approval date: 5/25/2021 Effective Date: 5/25/2021		<b>Euclid Hospital:</b> Board approval date: 5/25/2021 Effective Date: 5/25/2021	
<b>Fairview Hospital:</b> Board approval date: 5/25/2021 Effective Date: 5/25/2021		<b>Hillcrest Hospital:</b> Board approval date: 5/25/2021 Effective Date: 5/25/2021	
<b>Lutheran Hospital:</b> Board approval date: 5/25/2021 Effective Date: 5/25/2021		<b>Marymount Hospital:</b> Board approval date: 5/25/2021 Effective Date: 5/25/2021	
<b>Marymount Hospital:</b> Board approval date: 5/25/2021 Effective Date: 5/25/2021		<b>South Pointe Hospital:</b> Board approval date: 5/25/2021 Effective Date: 5/25/2021	
<b>CCCHR:</b> MEC approval date: 5/25/2021 Board approval date: 5/25/2021 Effective Date: 5/25/2021		<b>Weston, Florida:</b> MEC approval date: 5/25/2021 Board approval date: 5/25/2021 Effective Date: 5/25/2021	
<b>Mercy Hospital:</b> Board approval date: 11/17/2021 Effective Date: 5/9/2022		<b>Coral Springs, FL ASC/FHC:</b> MEC/CSOC approval date: 5/25/2021 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 in research. This policy applies to [Investigators](#), which means any Target Group member of the Professional [Staff](#), [employed physician](#), other [Employee](#) or [Trainee](#) participating in research and includes the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research performed under the auspices of our Organization's locations which have adopted this policy, which may include outside collaborators with, or outside consultants to our Target Group's [Staff](#), [Employees](#) or [Trainees](#).

## Policy Statement

### Presumption Against Participating in Research When Personal Financial Interests Exist

If an [Investigator](#) has a [Significant Financial Interest](#) ("SFI") and that SFI is considered to be a [Conflict of Interest](#) (or a Public Health Service ("PHS")-Reportable Financial Conflict of Interest; see below), the Investigator must obtain approval from the IM&COI Program to participate in human subjects or non-human subjects research.

## 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

A [Significant Financial Interest](#) ("SFI") in a [Non-Cleveland Clinic \(CC\) Entity](#) is one or more of the following Financial Interests of an [Investigator](#) (or [Immediate Family](#) member or entity controlled by any of them):

- [Honoraria or Consulting Compensation Exceeding \\$5,000](#) in the previous 12 months, from a single Non-CC Entity, including speaking, advising, other fees for services, paid authorship and other remuneration\* - whether cash or non-cash,
- [Equity](#) – Including stock, stock options, or other ownership interests of any amount,
- [Royalties](#) – Royalty payments or the written contractual right to future royalties or other income related to intellectual property rights and interests, including licensing and option agreement fees,
- [Payments Not Described in the Research Contract](#),

- [Fiduciary Service](#)\*\* – An appointment as an officer, chief medical officer, director, trustee, partner, or governing board member, whether compensated or not.

The term SFI does not include income from seminars, lectures, teaching engagements or service on advisory committees or review panels sponsored by United States government agencies (for example, NIH Study Sections); United States institutions of higher education as defined at 20 U.S.C. 1001(a); academic teaching hospitals; medical centers; or research institutes that are affiliated with an institution of higher education. Income from these sources does not need to be disclosed to the IM&COI Program. This exclusion does not apply to relationships with foreign governments or foreign institutions of higher education, academic teaching hospitals, medical centers or research institutes affiliated with an institution of higher education. A Conflict of Interest exists when:

- the [Investigator](#) has a [SFI](#) in the commercial sponsor of the research or any other [Financially Interested Company](#). (This includes the manufacturer of products under investigation or in use in the study); or
- the [Investigator](#) has a [SFI](#) that could be affected by the research.

A PHS-Reportable Financial Conflict of Interest exists if the IM&COI Program finds that the [Conflict of Interest](#) could directly and significantly affect the design, conduct, or reporting of the research.

Note that while the following situations could create a [Conflict of Interest](#), they do not create a PHS-Reportable Financial Conflict of Interest:

- [Royalties](#) to be paid by our Organization to the [Investigator](#) if the [Investigator](#) is employed by our Organization
- [Fiduciary Service](#)
- [Payments Not Described in the Research Contract](#)
- For a publicly traded entity, if the sum of compensation received in the previous 12 months and the current value of any equity interest in the entity, as of the date of the disclosure, does not exceed \$5,000

When either a [Conflict of Interest](#) or a PHS-Reportable Financial Conflict of Interest exists, the [Investigator's](#) participation or continued participation in the research must be approved by the IM&COI Program.

For either [Human or Non-Human Subjects Research](#), approval may be granted only if the IM&COI Program determines that a Conflict Management Plan (or a PHS-Reportable Conflict Management Plan) will, to the extent possible, ensure that the design, conduct or reporting of the research will be free from bias that may result from the [Conflict of Interest](#) (or PHS-Reportable Conflict of Interest). The [Investigator](#) would be allowed to participate in the research only pursuant to a Conflict Management Plan or a PHS-Reportable Conflict Management Plan, subject to modification by the Institutional Review Board (“IRB”), as applicable. The IM&COI

Program will monitor compliance with such Conflict Management Plans or PHS-Reportable Conflict Management Plans.

## **Additional Requirements for Human Subjects Research**

For [Human Subjects Research](#), in addition to the approval and management requirements above, the IM&COI Committee must find [Compelling Circumstances](#) to justify the Investigator's participation in the research when the Conflict of Interest or PHS-Reportable FCOI results from certain types of [SFIs](#). Those [SFIs](#) are: [Equity, Royalties, Payments not Described in the Research Contract, Fiduciary Service, or Honoraria and Consulting Compensation](#) Exceeding \$20,000 in the previous 12 months from a single [Non-CC Entity](#). [Compelling Circumstances](#) are those facts that convince the IM&COI Program that the [Investigator](#) may participate in the [Human Subjects Research](#) despite the [Conflict of Interest](#) or PHS-Reportable Financial Conflict of Interest.

## **Disclosure**

[Investigators](#) participating in research must submit disclosures of all Financial Interests (whether SFI or not) in [Non-CC Entities](#) annually as well as within 30 days of a material change in Financial Interests. The initial disclosure must occur prior to participating in research. The IM&COI Program will review all disclosures and, in consultation with the discloser, determine whether any of the Financial Interests that are [SFIs](#) constitute a Conflict of Interest or PHS-Reportable Financial Conflict of Interest.

## **Travel Disclosure for Investigators participating in Research Supported by the PHS**

PHS [Investigators](#) are required to complete meeting attendance forms when traveling related to their [Institutional Responsibilities](#) and the travel is reimbursed or sponsored by [Non-CC Entities](#), regardless of whether the Investigator is using vacation or other personal time. These forms must specify the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. For PHS [Investigators](#), travel sponsored or reimbursed by a [Non-CC Entity](#) is considered a [SFI](#).

## **Retrospective Review and Mitigation Reports**

Whenever the IM&COI Program becomes aware of a PHS-Reportable Financial Conflict of Interest that was not timely disclosed or was not timely identified while research is ongoing, the [Investigator](#) would be allowed to participate in the research only pursuant to a PHS-Reportable Conflict Management Plan.

In the cases of such noncompliance involving PHS-funded research, the IM&COI Program will have a PHS-Reportable Conflict Management Plan in place within 60 days of the disclosure or review of the [SFI](#). In addition, within 120 days of the finding of such noncompliance, or a finding of noncompliance with a PHS-Reportable Conflict Management Plan, the IM&COI Program will complete and document a retrospective review of the [Investigator's](#) activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct or reporting of such research. If bias is found, the IM&COI Program will provide the required notification and mitigation report to the PHS Awarding Component.

In the cases of such noncompliance involving non-PHS-funded research, the parameters of the retrospective reviews will be determined on a case-by-case basis at the discretion of the IM&COI Program.

### **Public Accessibility**

For PHS-funded research, the IM&COI Program will make available via a publicly accessible website or written response within five business days of request, information concerning any PHS-Reportable Financial Conflict of Interest with respect to senior/key personnel identified by the IM&COI Program. This information will be updated at least annually, and each time senior/key personnel disclose a relevant change. The information concerning the PHS-Reportable Financial Conflict of Interests on this publicly accessible website or in response to written requests will remain available for at least three years from the date that the information was most recently updated.

### **Disclosures to the Scientific Community**

Compensation of any amount from a research sponsor or other [Financially Interested Company](#) (any entity with financial interests that would reasonably appear to be affected by the conduct or outcome of the research) as well as the existence of a Conflict of Interest or PHS-Reportable Financial Conflict of Interest in research, must be disclosed as follows and as applicable: in or with a manuscript submitted for publication; in any substantive public presentation of the research results; in or with any medical or public presentation that references products of the sponsor or other [Financially Interested Company](#) used in the research; to research funders or sponsors; to the government as required by law; and to the principal investigator, co-investigators, collaborators, and other research personnel working on the research project. For [Human Subjects Research](#), disclosures are also required in IRB-approved consent forms, as required by the IRB, with an explanation that additional information would be provided to the research subjects upon request; to the sponsor of multi-center trials; and to the IRBs of the other participating institutions.

### **Training**

Pursuant to federal conflict of interest regulations, the IM&COI Program will provide COI training to [Investigators](#) on PHS-funded research projects. [Investigators](#) on PHS-funded research projects will undergo training prior to engaging in research and at least every four years thereafter, and immediately (at the next available training session) whenever: there is a change to this policy; the [Investigator](#) is new; or the [Investigator](#) is found to be not in compliance with this policy, Conflict Management Plan or PHS-Reportable Conflict Management Plan. COI training will be provided to other [Investigators](#) as deemed appropriate by the IM&COI Program.

### **No Royalty Payments or other Commercialization Revenues for use at our Organization of Products Commercialized by our Organization or developed by its Employees**

CCUS (and other locations who have adopted that policy) [Staff](#), [Employees](#) and [Trainees](#) involved in the development of intellectual property may be entitled to royalty payments and/or other commercialization revenues. Our Organization will not retain for its own use any royalties paid to our Organization, derived from products used, sold or purchased by our Organization. [Staff](#), [Employees](#) and [Trainees](#) may not receive royalty revenue from products used, sold or purchased at or by our Organization. These royalty payments will be directed to the Cleveland Clinic Innovators' Charitable Fund the mission of which is to support outside charitable purposes (e.g. donations to the American Red Cross). Book royalties received by [Staff](#), [Employees](#) or [Trainees](#) for use of their published material in teaching endeavors at our Organization must also be directed to the Cleveland Clinic Innovators' Charitable Fund at the discretion of the IM&COI Program. 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.

### **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.

\* [Honoraria and Consulting Compensation](#) of any amount paid to Investigators is subject to the approval requirements of [Policy V](#).

\*\*[Fiduciary service](#) as an officer or member of an external board of directors requires pre-approval in accordance with the policy entitled, "[Membership on Boards of Directors in Outside, For-Profit Businesses and Corporations](#)," for members of the Professional Staff.

### **Regulatory Requirement/References**

Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors, 76 Fed. Reg. 53,256 (Aug. 25, 2011) (codified at 42 C.F.R. Part 50 Subpart F and 42 C.F.R. Part 94).

### **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.

Principal Investigators share responsibility with the Innovation Management and Conflict of Interest Program for ensuring compliance with this policy on their projects

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.