



Innovation Management and Conflict of Interest Program

Policy IV – Institutional Conflicts of Interest in Research Policy

Target Group: Cleveland Clinic United States Locations		Original Date of Issue: August 23, 2012	Version 3 2
Approved by: Board of Governors	Date Last Approved/Reviewed: 1/27/2016	Prepared by: Cory Schmidt, J.D., Director, COI Compliance	Effective Date 2007

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 institutional conflicts of interest in research.

Policy Statement

Presumption Against Conducting Research When Our Organization Holds Institutional Financial Interests

A [Human or Non-Human Subjects Research](#) project in which our Organization has an [Institutional Financial Interest](#) 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) is subject to the approval of the Innovation Management and Conflict of Interest (“IM&COI”) Program. If the IM&COI Program grants approval for the research to proceed, a Conflict Management Plan may be required.

Definitions

Target Group - herein defined as Cleveland Clinic United States locations- Includes the main campus, Avon, Euclid, Fairview, Hillcrest, Lakewood, 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

Institutional Financial Interests

An [Institutional Financial Interest](#) occurs when one or more of the following circumstances exists (as more fully defined in the Glossary):

- Our Organization receives **royalties** from the sale of a product that is or was under investigation at our Organization
- Our Organization holds any **equity** in a non-publicly traded sponsor of current Target Group research
- Or*
- Our Organization holds **equity** exceeding \$100,000 in a publicly traded sponsor of current Target Group research

Significant Financial Interests of Officials

When an [Official](#) of Cleveland Clinic – main campus (or Immediate Family member or controlled entity), whether or not participating in research, has one or more of the following [Significant Financial Interests](#) listed below in a sponsor of research at the Target Group or other [Financially Interested Company](#) (this includes the manufacturer of products under investigation or in use in the study) the IM&COI Program may review the [SFI](#) to determine whether an Institutional Conflict of Interest requiring a Conflict Management Plan exists.

- Honoraria, compensation from consulting, speaking, advising, other fees for services, paid authorship and other remuneration over \$20,000 per year* whether cash or noncash,
- Any Equity, including stock, stock options, or other ownership interests of any amount, or 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, from a non-publicly traded entity,
- Equity or royalties exceeding \$20,000 from a single publicly traded entity,
- Payments involving the research project not specified in the contracting document, or
- [Fiduciary Service](#)** such as an appointment as an officer, chief medical officer, director, partner, or governing board member, whether compensated or not.

Disclosing to IM&COI Program

- **Disclosures by [Officials](#) and Committee Members** – Cleveland Clinic – main campus [Officials](#) and members of the IRB, IACUC, and IM&COI Committee must annually report to the IM&COI Program (with prompt interim updating) all [Significant Financial Interests](#) (“SFIs”) or “other reportable relationships” that they (or their [Immediate Family](#) members) have in sponsors (or the sponsors’ direct and primary competitors) of current or anticipated Target Group [Human Subjects Research](#) or [Non-Human Subjects Research](#), whether or not they are involved in the research.

- **Other Reportable Relationships** – Any Target Group Staff member or Employee who has an “other reportable relationship” should report that relationship to the IM&COI Program. The following (referred to as “other reportable relationships”) are not necessarily

[Institutional Financial Interests](#) but are nonetheless disclosable to the IM&COI Program by any Target Group [Staff](#) member or [Employee](#) who, on behalf of our Organization:

- Participates in purchases from a sponsor of the Target Group [Staff](#) member's or [Employee](#)'s research
- Receives a substantial gift or grant from a research sponsor – including equity or partnership interests

Disclosures to Research Subjects and the Scientific Community

To the extent required by the IM&COI Program, the existence of an [Institutional Financial Interest](#) in [Human](#) or [Non-Human Subjects Research](#) that has been approved by the IM&COI Program must be disclosed as follows and as applicable:

- In IRB-approved consent forms, as required by the IRB, with an explanation that additional information will be provided to the research subjects upon request
- In or with a manuscript submitted for publication concerning the research
- In any substantive public communication of the research results
- To the principal investigator, co-investigators, collaborators, other research personnel working on the research project
- To the sponsor of multi-center trials
- To the IRBs and IACUCs of the other participating institutions.

* [Honoraria and Consulting Compensation](#) of any amount paid to Target Group [Staff](#) 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](#)."

Appendices

Regulatory Requirements/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.

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.