Purpose

To assure professional and commercial integrity in all matters, Cleveland Clinic United States (CCUS) maintains a program that identifies and addresses conflicts of interest in research. This policy applies to Investigators, which means any CCUS Staff, 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 CCUS, which may include non-CCUS collaborators with, or non-CCUS consultants to CCUS 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

Cleveland Clinic United States locations- Includes the main campus, Avon, Euclid, Fairview, Hillcrest, Lakewood, Lutheran, Marymount, Medina, South Pointe, Children’s Hospital for Rehabilitation, Cleveland Clinic Florida, Cleveland Clinic Hospital (Weston), and all Family Health Centers, Physician practice sites, Nevada practice sites, Emergency Departments, 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 government agencies (for example, NIH Study Sections); 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. 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 CCUS to the Investigator if the Investigator is employed by CCUS

- **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 to CCUS

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 Institution. 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 CCUS policy; the Investigator is new to CCUS; or the Investigator is found to be not in compliance with CCUS 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 CCE of Products Commercialized by CCUS or developed by CCUS Employees

Pursuant to the CCF Intellectual Property and Commercialization Policy, CCUS Staff, Employees and Trainees involved in the development of intellectual property may be entitled to royalty payments and/or other commercialization revenues. CCUS will not retain for its own use any royalties paid to CCUS, derived from products used, sold or purchased by Cleveland Clinic Enterprise (CCE). CCUS Staff, Employees and Trainees may not receive royalty revenue from products used, sold or purchased at or by CCE. These royalty payments will be directed to the Cleveland Clinic Innovators’ Charitable Fund, administered by CCUS, the mission of which is to support non-CCE charitable purposes (e.g. donations to the American Red Cross). Book royalties received by CCUS Staff, Employees or Trainees for use of their published material in teaching endeavors at CCE 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 CCUS or its Healthcare Providers for the purchase and use of products at locations other than CCE.

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.”
Regulatory Requirement/References


Oversight and Responsibility

The Office of Professional Staff Affairs is responsible to review, revise, update, and operationalize this policy to maintain compliance with regulatory or other requirements.

Principal Investigators share responsibility with the Office of Professional Staff Affairs 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.