

Appendix C: Glossary of Terms

Policies on Innovation Management and Conflicts of Interest

ACCME means Accreditation Council for Continuing Medical Education.

Cleveland Clinic Akron General Health System (AGHS) means Physician Partners Group, Akron General Partners, Visiting Nurse Service, Hospice, Home Care, and all locations reporting to these facilities. Akron General Medical Center (AGMC), AGMC provider based locations, Lodi Community Hospital and Lodi Community Hospital provider based locations are not included.

Cleveland Clinic Akron General Medical Center (AGMC) means Akron General Main Campus and any and all Akron General provider based locations.

Cleveland Clinic Indian River Hospital means Indian River Hospital and any and all Indian River Hospital provider based locations, including the hospital, ambulatory facilities, and all physician practices reporting to these facilities.

Cleveland Clinic Union Health System means all departments and clinical locations under Cleveland Clinic Union Health System that are located off the main hospital campus and the following departments, regardless of location: all physician practice offices, Work Well Occupational Medicine, Behavioral Health, Health Plex (PT), First Care Urgent Care, Home Care and Union Pharmaceutical Care, Inc.

Cleveland Clinic Union Hospital means inpatient units and other hospital departments of Cleveland Clinic Union Hospital that are located on the main hospital campus.

Cleveland Clinic United States locations (CCUS) Includes the main campus, Avon, Euclid, Fairview, Hillcrest, Lutheran, Marymount, Medina, 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.

Compelling Circumstances means those facts that convince the IM&COI Committee that proposed research may be conducted despite the existence of certain Significant Financial Interests. Considerations that may be evaluated by the IM&COI Committee in determining whether the proposed research may be conducted are listed in Appendix A, "Operating Guidelines of the IM&COI Committee."

A **Conflict Of Interest** may exist when a Target Group Staff member, Employee, Trainee, Investigator, or a member of his or her Immediate Family or an entity directed or controlled by any of them, has an interest—whether investment, compensation, or otherwise—in (including relationships with) a Non-CC Entity that could be reasonably perceived as influencing his or her activities in patient care, education, research, administrative decisions, or business transactions for CCUS.

Employee means an Official, employee, agent, or administrator. For purposes of these policies, Employee does not refer to members of the Professional Staff.

Financial Investment Firm means an entity that provides investment services to the public, including brokerage firms and hedge funds. Private equity or venture capital firms that evaluate new technologies for their own benefit are not considered Financial Investment Firms.

Financially Interested Company means an entity with financial interests that would reasonably appear to be affected by the conduct or outcome of research. This term includes the manufacturer (including business partners) of the drug or the device or other sponsor of the research. This term includes any entity acting as the agent of a Financially Interested Company, e.g., a contract research organization. This term also includes companies that provide direct and primary competition for the investigational product, if the Staff member, Employee, Trainee or Investigator actually knows that the financial interests of such a company would reasonably appear to be affected by the research.

Healthcare Provider means Target Group Professional Staff, residents and fellows who provide healthcare to patients.

Honoraria and/or Consulting Compensation means direct or indirect compensation—e.g., honoraria, lecture fees, consulting fees, stock or stock options, royalties, or “in kind” compensation—received by a Staff member, Employee or Trainee (or his or her Immediate Family member) or any foundation, trust, or other entity controlled or directed by the Staff member, Employee or Trainee (or Immediate Family member) from a Non-CCHS Entity for an activity performed by the Staff member, Employee or Trainee related to his or her Institutional Responsibilities.

Human Subjects Research means a systematic investigation performed with human subjects (including development, testing, and evaluation) designed to develop or contribute to generalizable knowledge, regardless of the source of funding or whether the research is subject to federal regulation. For purposes of this Policy, the term “Human Subjects Research” includes clinical investigations and experiments regulated by the U.S. Food and Drug Administration that involve any of the following for human use: a drug, biological product, medical device, human food or color additive, electronic product, and any other regulated test article.

Immediate Family means a Target Group Staff member, Employee or Trainee and his or her spouse, domestic partner, dependent children, and other dependents.

Institutional Financial Interest means one of the following:

- **Royalties** – When the Organization or a subsidiary is entitled to receive royalties (payments linked to the sale of a product) or other revenues from commercialization of a product that is or was under investigation at the Organization.
- **Any Equity in a Non-publicly Traded Entity** – When, through the Organization’s technology licensing activities or investments related to such activities, the Organization or a subsidiary has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a Non-publicly traded Entity.
- **Equity Exceeding \$100,000 in a Publicly-traded Entity** – When, through the Organization’s technology licensing activities or investments related to such activities, the Organization or a subsidiary has obtained an equity interest or an entitlement to equity (including options or warrants) of value exceeding \$100,000 in a publicly-traded Entity. Exception: Mutual Funds and Fiduciary-Managed Funds – Interests of any amount in publicly-traded, diversified mutual funds or in funds in which the investment decision-making is made by fiduciary managers appointed by the Organization but not otherwise affiliated with the Organization are not Institutional Financial Interests.
- **Significant Financial Interests of Cleveland Clinic** – main campus Officials – When a Cleveland Clinic main-campus Official (or Immediate Family member or controlled entity), whether participating in research or not, holds a personal Significant Financial Interest (“SFI”) in any Non-CC Entity. Exception: having equity or royalties up to \$10,000 per year from a publicly-traded research sponsor is not an Institutional Financial Interest.

Institutional Responsibilities means an individual’s professional responsibilities on behalf of CCE, which may include, for example: activities such as research, research consultation, teaching, professional practice (including, for example, clinical practice, administrative duties and purchasing related activities), institutional committee memberships and service on panels, such as the Institutional Review Board or data and safety monitoring boards.

Investigator means any Target Group 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 the Organization, which may include non-CC collaborators with, or non-CC consultants to Target Group Staff, Employees or Trainees.

Lodi Community Hospital (Lodi) means Lodi Community Hospital and Lodi Community Hospital provider based locations.

Non-Cleveland Clinic (Non-CC) Entity means a party that is outside of the Organization and that engages in business or research that relates to the mission, business or interests of the Organization or could reasonably be perceived as related to a Target Group Staff member’s, Employee’s, Trainee’s, or Investigator’s Institutional Responsibilities, and includes, but is not limited to, pharmaceutical, diagnostic, device and biotechnology

companies, health care or wellness entities, technology companies (including hardware and software companies and makers of wearable devices), a spin-off and venture partner companies of the Organization, medical education companies, medical publishing groups, financial investment firms and entities that broker for them, Organization corporate donors, other entities that provide healthcare, and major vendors of the Organization.

Non-Human Subjects Research means basic research, animal research, or other research that is not Human Subjects Research.

Officer means one of the following persons: President and Chair of the Board of Governors, Vice Chairman of the Board of Governors/Chief of Staff, Chief Operating Officer, Chief Financial Officer, Secretary, Assistant Secretary, Treasurer, and Controller of Cleveland Clinic – main campus. Officers are elected by the Board of Directors and are subject to the conflict of interest disclosure and management requirements of the Board of Directors in addition to being subject to these policies.

Official means one of the following persons: an Officer of Cleveland Clinic – main campus, the Chair of CC Innovations, all Institute and Department Chairs.

Organization means *Cleveland Clinic United States locations; Cleveland Clinic Akron General Health System; Cleveland Clinic Akron General Medical Center; Lodi Community Hospital; Union Hospital Association; Union Health System; Cleveland Clinic Indian River Hospital*; any other facility directly or indirectly owned or controlled by the Cleveland Clinic Foundation and located in the United States; and any and all Target Groups that have adopted these policies.

Scientific Advisory Board or Committee includes such committees as a data safety monitoring board, a steering committee for a clinical trial, an executive committee for a clinical trial, or other committee of a Non-CC Entity. Service on a Scientific Advisory Board or Committee is not “fiduciary service” as discussed in these policies; however, service on a Scientific Advisory Board or Committee, if compensated, does require compliance with Policy V, “Consulting.”

Significant Financial Interest means one or more of the following interests of a Target Group Staff member, Employee, Trainee or Investigator (or Immediate Family member, or any foundation, trust, or other entity controlled or directed by any of them) in a Non-CC Entity. Salary from the Organization and cost-related payments for services or reimbursement from the Organization are not Significant Financial Interests.

- **Honoraria or Consulting Compensation Exceeding \$5,000** – Consulting fees, honoraria, lecture fees, paid authorship, or “in kind” compensation directly or indirectly from a single Non-CCHS Entity (or entitlement to the same), whether for consulting, lecturing, service on a Scientific Advisory Board or Committee, or for any other purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement), that in the aggregate have in the prior 12 months exceeded \$5,000. Honoraria or Consulting Compensation does not include reimbursement for actual travel costs.

- **Equity** – Equity interests held either directly or indirectly, including stock and stock options, of any amount in either a publicly-traded or non-publicly-traded Financially Interested Company (or entitlement to the same).
(Exception: Mutual Funds and Fiduciary-Managed Funds – Interests of any amount in publicly-traded, diversified mutual funds or in funds in which independent fiduciary managers make the investment decisions are not Significant Financial Interests.)
- **Royalties and Other Revenues from Commercialization** – Royalty income (payments linked to product sales), the written contractual right to receive future royalties, or other income that is related to intellectual property rights and interests, directly or indirectly under a patent, license or copyright.
- **Payments Not Described in the Research Contract** – Any non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (as specified in the agreement between the sponsor and the Organization). This includes any bonus or milestone payments to a Target Group Staff member or Employee in excess of reasonable costs incurred in the research. (Milestone payments that are contingent upon the achievement of particular research results are absolutely prohibited.)
- **Reasonable Research Costs** – Payments to the Organization, or via the Organization to the Target Group Staff member, Employee, or Trainee that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement(s) between the sponsor and the Organization are not Significant Financial Interests.
- **Fiduciary Service** – An appointment to serve, in either a personal or representative capacity, as an officer, director, partner, or governing board member of a Non-CC Entity whether or not compensation is received for such service. (Members of the Professional Staff are also subject to the policy entitled “Membership on Boards of Directors in Outside, For-Profit Businesses and Corporations” contained in the Major Policies for the Professional Staff.) Service on a Pharma Advisory Committee is not “fiduciary service;” however, service on a Pharma Advisory Committee, if compensated, does require pre-approval and compliance with Policy V, “Consulting.”

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; institutions of higher education as defined at 20 U.S.C. 1001(a); United States academic teaching hospitals; medical centers; or research institutes that are affiliated with an institution of higher education.

Staff means a member of the Professional Staff.

Target Group means the Organization’s locations and entities that have adopted and are subject to these policies.

Trainee includes medical students, clinical trainees such as interns, residents, and clinical fellows, post-doctoral fellows and research associates who are receiving training at any Target Group location and also can include other learners receiving instruction, such as Staff.