IM&COI POLICY III

CONFLICTS OF INTEREST
IN RESEARCH

(Capitalized terms are defined in the Glossary.)

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.

Significant Financial Interest

A Significant Financial Interest ("SFI") in a Non-CCHS 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-CCHS 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 CCHS to the Investigator if the Investigator is employed by CCHS
• 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-CCHS 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 CCHS**

Investigators participating in research must submit disclosures of all Financial Interests (whether SFI or not) in Non-CCHS 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 CCHS meeting attendance forms when traveling related to their Institutional Responsibilities and the travel is reimbursed or sponsored by Non-CCHS 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-CCHS 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 CCHS policy; the Investigator is new to CCHS; or the Investigator is found to be not in compliance with CCHS 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.

* 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.”
POLICIES ON INNOVATION MANAGEMENT AND CONFLICTS OF INTEREST

APPENDIX A

OPERATING GUIDELINES OF INNOVATION MANAGEMENT & CONFLICT OF INTEREST PROGRAM

(Capitalized terms are defined in the Glossary.)

Innovation Management & Conflict of Interest (“IM&COI”) Committee Governance – The IM&COI Committee’s members, including alternates and Chair, are nominated by the Chief of Staff’s office after consultation with the (Staff) IM&COI Committee, and are appointed by the Board of Governors. The Director of the IM&COI Program, who is also the Chair of the IM&COI Committee, will report to the Chief of Staff regarding the activities of the Program and Committee. The Director of the IM&COI Program shall provide reports of its activities to the Board of Governors and to the Board of Directors Conflict of Interest and Managing Innovations Committee annually or more frequently if requested.

The ultimate authority regarding conflict of interest activities resides with the Board of Directors Conflict of Interest and Managing Innovations Committee.

IM&COI Committee Members – The IM&COI Committee membership should include the following representation: at least one member of the CCHS Professional Staff who does not conduct Human Subjects Research; at least two representatives from the Board of Directors; the chair or vice chair of the Institutional Review Board (“IRB”); at least one attorney from the Law Department; a representative from the Office of Professional Staff Affairs (“OPSA”); a representative from the Office of Corporate Communications; and a representative from CC Innovations (non-voting for institutional conflicts). For consideration of Institutional Financial Interests at least one of the Board of Directors members must vote as part of the majority for any approvals. One of the two Directors members is the Chairman of the Conflict of Interest and Managing Innovations Committee of the Board of Directors and the other is selected by him or her. CC Innovations representatives may deliberate but not vote on Institutional Financial Interests. Recusal is required whenever any member has a conflict of interest regarding any matter under review.

Review Process – The IM&COI Program reviews any disclosure or request for an activity involving interests that may result in a Conflict Of Interest, including Significant Financial Interests (“SFIs”) and Institutional Financial Interests in research, clinical, administrative, and educational activities. The IM&COI Program also determines whether the proposed activity may proceed and may impose restrictions on the activity. The IM&COI Program may confer with individuals to discuss their interests and activities. For Institutional Financial Interests involving CCHS Officials, the Official’s research-related financial interests and leadership roles will be scrutinized. The IM&COI Committee shall collaborate with the Conflict of Interest and
Managing Innovations Committee of the Board of Directors to develop an appropriate Conflict Management Plan or PHS-reportable Conflict Management Plan for each interest disclosed by a Director or Trustee that raises a potential conflict of interest or Conflict of Interest in research, medical education, administration, or the practice of medicine or surgery. The following lists of factors to consider and optional management strategies are provided as resources that may (or may not) be used by the IM&COI Committee, at its discretion, in evaluating whether a research project may be conducted when Conflict of Interests, Financial Conflicts of Interest and Institutional Financial Interests have been identified:

**Factors to Consider in Evaluations**

- A description of the research, including the risks to human subjects involved in the research
- Any unique expertise of the investigator, e.g., inventorship, that may make his or her involvement essential
- The nature and amount(s) of the Financial Interest that are related to the research
- The potential financial gains in the immediate and long-term future in the event the research is successful
- The extent to which the design, conduct or reporting of the research could be influenced by the Financial Interest
- The steps proposed for effective oversight and management of the PHS-Reportable Financial Conflict of Interest or Conflict of Interest
- Whether CCHS is uniquely qualified (by special facilities or equipment, unique patient population, qualifications of its investigators, etc.) to conduct the research and safeguard the research subjects

**Examples of Optional Management Strategies – For Investigators and CCHS Institutional Officials**

- Disclosure of SFIs to others working on the research; to the sponsor; in publications and presentations
- Disclosure of SFIs in research informed consent documents
- Reduction of role on Scientific Advisory Boards, e.g., ex officio, non-voting Restriction of Honoraria and Consulting Compensation, e.g., to less than $5,000 per year
- Reduction or divestiture of equity in company, including stock and options
- Reduction or elimination of royalty income
- Restriction from fiduciary service, such as an officer or director
- Annual report to IM&COI Committee on compliance with a management plan
- Recusal in all matters related to the research study (if CCHS Official and non-investigator)
- Appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of the research against bias
- Modification of the research plan
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research
Examples of Additional Optional Management Strategies – For the Institution

- Reduction or elimination of royalties from the sale of the investigational product
- Divestiture of equity if sponsor is non-publicly traded, including options or warrants
- Reduction of equity to less than $100,000 if sponsor is or becomes publicly-traded
- Limitation on the proportion of the research subjects enrolled at CCHS and/or not serving as the coordinating site
- Use of a data and safety monitoring board composed entirely or partially of non-CCHS members
- External IRB approval in addition to the approval of CCHS’ own IRB

When the IM&COI Committee determines that the research or other activity may proceed, the IM&COI Committee provides management of the potential Conflict of Interest or PHS-Reportable Financial Conflict of Interests related to the research or other activity. This may include periodic compliance audits and will include periodic reviews as stipulated by the IM&COI Committee or the research funding agency. The IM&COI Committee, with the advice of the Law Department, approves a Conflict Management Plan or PHS-Reportable Conflict Management Plan that includes the financial interest, the conditions under which the activity may proceed, and the individuals subject to the Plan (the “Interested Parties”) as well as a brief summary of the Plan (“Summary Report”). Conflict Management Plans may describe the depth and frequency of any compliance audits. Any changes in the Plan require IM&COI Committee approval. The Board of Directors provides joint oversight and management (with the IM&COI Committee) of Conflict Management Plans or PHS-Reportable Conflict Management Plans involving Interested Parties who are CCHS Officers. The IM&COI Committee distributes copies of the Plan (including the Summary Report) to the Interested Parties, the Law Department, OPSA, and the IRB upon request. The IM&COI Program will provide the Financial Interests of Professional Staff to their Department Chair. IRB representatives who are members of the IM&COI Committee may reveal to the IRB the precise amount and nature of a Financial Interest. The IM&COI Program may perform audits to ensure Conflict Management Plan or PHS-Reportable Conflict Management Plan compliance and full and accurate disclosure of Financial Interests, leadership roles, and/or Institutional Financial Interests by CCHS Staff members, Employees and Trainees.

Comparative Authority of IM&COI Committee, IRB, and IACUC – Neither the IRB nor the Institutional Animal Care and Use Committee (“IACUC”) may approve research that has been disapproved by the IM&COI Committee. Neither the IRB nor the IACUC may approve monitoring procedures or other conditions that are less protective of research subjects or animals than those imposed by the IM&COI Committee. No authorization granted by the IM&COI Committee may supersede the authority of either the IRB or the IACUC. The IRB or IACUC may impose more stringent restrictions upon research than those imposed by the IM&COI Committee. The IRB or IACUC may disapprove research despite a determination by the IM&COI Committee that the research activities may proceed.
 Appeals – Determinations of the IM&COI Committee may be appealed to the Board of Governors. Requests for appeal must be in writing and be submitted to the Chief of Staff, with a copy to the IM&COI Committee Chair. Determinations of the IM&COI Committee are in effect during the appeal. Decisions of the Board of Governors are final and are submitted in writing to the Staff member or Employee, the IM&COI Committee, the IRB or the IACUC, and the Staff member’s or Employee’s department chair. If the Board of Governors modifies the IM&COI Committee’s determination, the IM&COI Committee modifies and reissues the Conflict Management Plan or PHS-Reportable Conflict Management Plan.

 Reporting by IRB – The IRB alerts the IM&COI Program whenever a Staff member, Employee or Trainee known to have a Significant Financial Interest proposes to conduct SFI-related human subjects research. The IRB withholds final approval of the research until informed of the IM&COI Committee’s determinations.

 Reporting by CC Innovations – Prior to executing a technology licensing agreement, CC Innovations informs the IM&COI Program of the proposed agreement. The IM&COI Program then reviews the matter.

 Protection from Discovery – The IM&COI Committee, the Board of Governors, and the IRB, while administering their responsibilities as described herein, are review committees described in O.R.C. Sec. 2305.25, entitled to the protections from discovery in legal proceedings afforded by law.
Intellectual Property and Publication Rights – CCHS Staff members and Employees are accountable for the integrity of publications that bear their names. A principal investigator may receive, analyze, and interpret all data generated in the research and publish the results, regardless of the outcome of the research. Neither CCHS, its Staff members, nor its Employees should enter research agreements that permit a research sponsor or other Financially Interested Company to require more than a reasonable time for pre-publication review, or that interfere with a Staff member’s or Employee’s access to the data developed at CCHS or ability to analyze that data independently. Members of the Professional Staff are also subject to the policies entitled “Guidelines for Manuscripts and Books,” “Commercial Publication of Medical Professional Works,” and “Intellectual Property and Commercialization Policy” contained in the Major Policies for the Professional Staff.

Medicare Fraud/ Referral Prohibitions – In general, federal law prohibits a person from knowingly and willfully offering or paying anything of value (direct or indirect) to any person to induce that person to refer or purchase, lease, order or arrange for services which are reimbursable by a federal health care program. The general purpose of the statute is to prohibit anyone from paying or accepting payment in exchange for the referral of Medicare or Medicaid patients. There are certain “safe harbors” identifying specific types of practices that would not violate federal law. For instance, certain consulting arrangements are permissible so long as the payment to the consultant is for legitimate services and in an amount that reflects the fair market value of the services. Also, commercial research sponsors or vendors may provide funding for research or other bona fide purposes to CCHS, even though CCHS may order supplies from that vendor. If the purpose of the funding is to induce referrals from CCHS, however, the funding would be prohibited. Federal law also broadly prohibits physicians from making certain referrals to entities with which they have a financial relationship unless a statutory exception applies. There are a series of exceptions that apply to this prohibition as well, e.g., a bona fide consulting agreement where specific requirements are met.

Insider Trading – The securities laws broadly prohibit fraudulent activities of any kind in connection with the offer, purchase, or sale of securities. These provisions are the basis for many types of government enforcement activities, including actions against illegal insider trading. Insider trading is illegal when a person trades a security while in possession of material nonpublic information, including information from medical research trials, in violation of a duty to withhold the information or refrain from trading in that security. “Tipping” other traders of such information who then trade a security affected by the tip is also illegal, as is acting on an illegal tip.
**Promotional Prohibitions** – Staff members and Employees who conduct FDA-regulated research are prohibited from representing in a promotional context that an investigational new drug, device, or other test article is safe or effective (or otherwise beneficial) before it has received regulatory approval. Press releases and other promotional disclosures prepared by commercial sponsors or manufacturers using the name of CCHS, its Staff members, or its Employees should be submitted to the Chief Marketing Officer for prior approval. Staff members are also subject to the policy entitled “The Use of the Foundation’s Name or Logo” contained in the Major Policies for the Professional Staff.

**Regulation of Profits on Test Articles** – Neither CCHS nor a research sponsor may charge for an investigational new drug, device, or other test article a price greater than necessary to recover certain costs.

**Mandatory Contract Review** – Written agreements, pre-approved by the Law Department, are required for all Staff Honoraria and Consulting of (a) more than $10,000 during a 12-month period from a single source or (b) any amount from Financial Investment Firms—for details see Policy V, “Consulting by the Professional Staff.” All other proposed written agreements regarding research should be submitted to the Office of Sponsored Research, which may triage the contracts to Law Department and/or CC Innovations as appropriate. This includes all research grants and contracts, training/fellowship agreements, clinical trial contracts, GCRC contracts, data analysis contracts, data use agreements (DUAs), confidential disclosure agreements (CDAs), material transfer agreements (MTAs), cooperative agreements, letters of intent, and related subcontracts.
POLICIES ON INNOVATION MANAGEMENT AND CONFLICTS OF INTEREST

APPENDIX C

GLOSSARY

(Capitalized terms are defined in the Glossary.)

ACCME means Accreditation Council for Continuing Medical Education.

CCHS includes, but is not limited to, The Cleveland Clinic Health System, its regional medical practice centers, Cleveland Clinic Florida, Lou Ruvo Center for Brain Health and their wholly-owned affiliates.

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 CCHS 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-CCHS Entity that could be reasonably perceived as influencing his or her activities in patient care, education, research, administrative decisions, or business transactions for CCHS.

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.
**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 source other than CCHS 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 CCHS 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 CCHS 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 CCHS.

- **Any Equity in a Non-publicly Traded Entity** – When, through CCHS’ technology licensing activities or investments related to such activities, CCHS 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 CCHS’s technology licensing activities or investments related to such activities, CCHS 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 CCHS but not otherwise affiliated with CCHS are **not** Institutional Financial Interests.

- **Significant Financial Interests of CCHS Officials** – When a CCHS Official (or Immediate Family member or controlled entity), whether participating in research or not, holds a personal Significant Financial Interest (“SFI”) in any Non-CCHS 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 CCHS, 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 CCHS 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 CCHS, which may include non-CCHS collaborators with, or non-CCHS consultants to CCHS Staff, Employees or Trainees.

**Non-CCHS Entity** means a party other than CCHS that engages in business or research that relates to the mission, business or interests of CCHS or could reasonably be perceived as related to a CCHS 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, CCHS spin-off and venture partner companies, medical education companies, medical publishing groups, financial investment firms and entities that broker for them, CCHS corporate donors, other entities that provide healthcare, and major CCHS vendors.

**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. 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 CCHS, the Chair of CC Innovations, all Institute and Department Chairs.

**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-CCHS 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 CCHS 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-CCHS Entity. Salary from CCHS and cost-related payments for services or reimbursement from CCHS 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

Adopted, Board of Governors, August 23, 2012
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 CCHS). This includes any bonus or milestone payments to a 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 CCHS, or via CCHS to the 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 CCHS 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-CCHS 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 government agencies; 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.

**Staff** means a member of the CCHS Professional Staff.
Trainee includes, but is not limited to high school students, undergraduates, graduate students, medical students, clinical trainees such as interns, residents, and clinical fellows, post-doctoral fellows and research associates who are receiving training at CCHS and also can include other learners receiving instruction.