## EC-45 - Objectivity in Research and Conflict of Interest Disclosure

Owner: Ethics and Compliance Department

### Policy

1. The MetroHealth System (MHS) strongly supports efforts to bring discoveries to society through research, scholarship, and other creative endeavors have enormous potential to benefit humankind. MHS encourages participation in research that may involve relationships with outside sources, however these relationships carry with them a potential for conflicts of interest. MHS seeks to ensure the integrity of research conducted by its workforce in order to sustain public confidence in that research. This policy seeks to accomplish these purposes by striking the proper balance between preserving academic freedom, encouraging outside scholarly and entrepreneurial activities, and the need to preserve the integrity of MHS and its faculty and staff.

### Purpose

2. The purpose of this document is to describe the policy on conflict of interest in research, to protect the MetroHealth System, its faculty, non-faculty employees, trainees, and human subjects in research, and to comply with all applicable local, state, and federal laws.

### Scope

3. This policy applies to all MHS faculty, employees, trainees, scholars, emeritus faculty, senior/key personnel and any other individuals, regardless of title or position, including sub grantees, contractors, and collaborators, who are engaged in sponsored research.

4. This policy does not apply to non-MHS faculty or medical or allied health students. They are covered by their respective institution's policies.

5. This policy does not apply to applications for Phase I support under the Small Business Innovation Research and Small Business Technology Transfer programs.

### Definitions

6. Close Relation means your spouse, domestic partner, child/children, grandchild/children, parents, parents-in-law, grandparents, grandparents-in-law, siblings, in-laws (brother(s), sister(s), son(s),daughter(s)), nieces, nephews, aunts, uncles, or cousins (whether by marriage, lineal descent or adoption), any dependent person (meaning any relative by marriage, lineal descent or adoption who receives, directly or indirectly, more than one-half of his or her support from you; or any individual claimed by you or your spouse as a dependent under the United States Internal Revenue Code) living in your household or any business associate. (Business Associate applies to any situation where there is a relationship with one or more persons or entities who act together to pursue a common business purpose. An outside employer is considered to be a business associate of MHS.)

7. Conflict of Interest means a financial or other personal consideration that may compromise or appear, to a reasonable person, to compromise one's professional judgment or integrity in a way that directly and significantly affects the design, conduct, or reporting of covered research.

8. Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

9. Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

10. Investigator means 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 funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

11. Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

12. Outside Source means for profit or not-for-profit organizations that are involved directly or indirectly with the healthcare industry including, but not limited to, hospitals, physicians, allied health providers, pharmaceutical companies, device manufacturers, biotech companies, software vendors, and referral sources to MHS.

13. Public Health Service (PHS) of the U.S. Department of Health and Human Services (DHHS) means the PHS of the DHHS and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

14. Remuneration means direct or indirect in the form of salary or any payment for services not otherwise identified as salary (such as consulting fees, honoraria, paid authorship, travel reimbursement, lecture fees, stock or stock options, royalties, or "in kind" remuneration) received from a source other than MHS that sponsors the research or that holds a financial interest in the subject of the research.

15. Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating to public health, including basic and applied research, behavioral research, social-sciences research, and product (ex: drug or device) development.

16. Sub recipient means any entity that provides property or services under contract for the direct benefit or use of MHS, including, but not limited to, sub grantees, collaborators, contractors, and consultants.

## Procedure

17. In addition to the policy outlined below, all MetroHealth System employees are held to the following MetroHealth System policies: Vendor and Conflict of Interest Policy, Code of Ethical Behavior Policy, and Conflict of Interest Policy. It is suggested that employees cross reference these to ensure compliance with MetroHealth System policies.
    - 17.1. Policy.
        - 17.1.1. Identification
            - 17.1.1.1. What is a conflict of interest in research?
              A conflict of interest in research exists when an individual covered by this policy has financial or other personal considerations that may compromise or appear, to a

reasonable person, to compromise the individual's professional judgment or integrity in a way that directly and significantly affects the design, conduct or reporting of research activities, or that might compromise or appear, to a reasonable person, to compromise MHS's responsibility to the public, the safety of research subjects, or the integrity of research.

17.1.1.2. What activities must be reported in the disclosure process?
Individuals covered by this policy who engage in research must report any Significant Financial Interest (SFI) that the individual, or a close relation of the individual, has in an outside entity.

With regard to publicly traded entities, a SFI exists if the value of any remuneration received from the entity in the 12 months preceding disclosure, when aggregated, exceeds $5,000. This includes:

17.1.1.2.1. Salary

17.1.1.2.2. Payment for Services, such as:

17.1.1.2.2.1. Consulting fees

17.1.1.2.2.2. Honoraria

17.1.1.2.2.3. Paid authorship

17.1.1.2.2.4. Travel reimbursement

17.1.1.2.2.5. Lecture fees

17.1.1.2.3. Equity interest, such as:

17.1.1.2.3.1. Stock

17.1.1.2.3.2. Stock option

17.1.1.2.3.3. Other ownership interest

17.1.1.2.4. Gift or favor

17.1.1.2.5. Intellectual property rights, such as:

17.1.1.2.5.1. Patents

17.1.1.2.5.2. Copyrights

17.1.1.2.5.3. Royalties from IP rights

17.1.1.2.5.4. Agreements to share in royalties from IP rights

7.1.1.3. With regard to non-publicly traded entities, the same standards as above apply, except that any equity interest in the entity is considered a SFI.

7.1.1.4. Whenever an individual covered by this policy has any doubt about whether or not an activity should be reported, the individual should report the activity to the Research Compliance Committee.

7.1.1.5. What activities are permitted without reporting?

7.1.1.5.1. Certain activities need not be reported. Typically these are activities not listed above and which are not expected to influence the individual's judgment.

7.1.1.5.2. Examples of activities in which individuals may engage without disclosure include the following:

7.1.1.5.2.1. Income, travel expenses and or remuneration from service on advisory committees or as a reviewer for a governmental and

recognized inter-governmental or academic entities or professional societies.

7.1.1.5.2.1. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined by 20 U.S.C. 1001(a), or an academic teaching hospital, medical center, or research institute affiliated with MHS.

7.1.1.5.2.1. Remuneration for reviewing scholarly manuscripts for publication by academic journals or presses.

7.1.1.5.2.1. Income from diversified mutual funds or retirement accounts if the individual is not responsible for directing investments.

7.1.1.5.2.1. Remuneration received through an awarded research grant or a clinical trial agreement administered through the institution.

17.2. Disclosure.

17.2.1. How and to whom to make reports.

The MHS reporting process for faculty, non-faculty, employees and administrators engaged in research is administered by the MHS Compliance Office. Conflict of Interest Disclosure Reports must be filed using the Conflict of Interest forms located within the MHS eIRB system. Each year, individuals covered by this policy must report, in writing, any activities listed in Section 17.1.1.

17.2.2. When to file a disclosure report.

17.2.2.1. Any individuals to whom this policy applies must file a disclosure report:

17.2.2.1.1. Before engaging in research at MHS;

17.2.2.1.2. No later than at the time of application for PHS-funded research or submission of the research proposal to the MHS IRB for review;

17.2.2.1.3. Within 30 days of becoming aware of or acquiring a new actual or potential SFI;

17.2.2.1.4. Within 30 days following the elimination of a previous SFI;

17.2.2.2. All individuals to whom this Policy applies, including those who have no conflicts or SFIs, must still submit a COI disclosure form at least annually.

17.3. Action:

17.3.1. Review Process:

17.3.1.1. The Assistant Director of Research Compliance will conduct an initial review of all reports received. If necessary, additional information may be obtained from the reporting individual or from other individuals in possession of relevant information.

17.3.1.2. The Assistant Direct of Research Administration – Compliance will then identify those activities that must be reviewed and approved by the Research Compliance Committee and those activities that may proceed without such review. The Assistant Director of Research Administration – Compliance will notify the Research Compliance Committee of those activities that require review and approval.

17.3.1.3. Conflicts of interest identified for individuals working in research will be reviewed by the Research Compliance Committee.

17.3.1.4. Conflicts of interest identified for non-applicable individuals (not working in research) will be reviewed by the Office of the General Counsel – see MHS Conflict of Interest Policy EC-4.

17.3.2. Approval Process:

17.3.2.1. After reviewing a reported activity, the Conflict of Interest may be approved without a management plan. In determining whether a management plan is required, the Research Compliance Committee will consider:

17.3.2.1.1. The significance of the conflict of interest (e.g., the size of the individual's financial interest);

17.3.2.1.2. Whether or not the individual is uniquely qualified by virtue of expertise and experience to conduct the research project;

17.3.2.1.3. Whether the research could be conducted as safely or effectively without that individual;

17.3.2.1.4. The degree of risk imposed on research subjects.

17.3.3. Management Plans:

17.3.3.1. The Research Compliance Committee may decide to approve a conflicted arrangement subject to a suitable management plan.

17.3.3.2. Management plans are developed according to the nature of the SFI and of the research (e.g., whether there is an institutional as well as an individual conflict of interest, and whether the investigator is conducting bench, animal or human subject research).

17.3.3.3. Before finalizing the management plan, the Research Compliance Committee will review the plan with the individual's Department Chair.

17.3.3.4. Management plans must be finalized and implemented within 60 days of MHS identifying a SFI (unrealistic) / Conflict of Interest.

17.3.3.5. Examples of conflict of interest management plan techniques can be found in Attachment A.

17.3.4. Appeal Process:

17.3.4.1. An individual may submit a written appeal of a decision to the Research Compliance Committee within 10 days of receipt of the decision.

17.3.4.2. If dissatisfied by the appeals decision, a written appeal may be submitted to the Chief Medical Officer within 10 days. If the CMO upholds the Research Compliance Committee's determination, the CMO's decision is final.

17.3.4.3. If the Research Compliance Committee and the CMO are unable to agree on the terms of a management plan, the matter is referred to General Counsel; and if the Research Compliance Committee is dissatisfied with the decision of the General Counsel, the Research Compliance Committee may refer the matter to the CEO.

17.3.5. Training:

17.3.5.1. All investigators must complete training prior to engaging in PHS-funded research at the MHS. New investigators must complete training upon becoming MetroHealth faculty. Additionally, investigators will be notified immediately of any revisions to this Policy that, in any manner, affects the requirements of investigators. Any individual to whom this Policy applies must complete COI training at least every four years. Training may consist of:

17.3.5.1.1. Online Training Slides on the MHS eIRB website
17.3.5.1.2. Online Training on the Collaborative Institutional Training Initiative (CITI) Program website
17.3.5.1.3. Live Training Sessions

## Cross Reference

FI-07 - Research Administration (Grants and Contracts)
EC-03 – Ethics and Compliance Training
EC-10 - Vendor Relations
HR-67 - Secondary Employment
42 CFR Part 50, Subpart F: http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

## Dates

Initiated August 2012

## Approved

President and Chief Executive Officer or Designee
Policy Committee

# Attachment A

## Examples of conflict of interest management plan techniques

- Requiring the individual to inform certain persons or institutions about the conflict of interest and the management plan (e.g., as the Office of Research Compliance, IRBs, IACUCs, subjects, state and federal officials, research sponsors, co-investigators, colleagues, junior colleagues, students, trainees, members and prospective members of the individual's research laboratory, journals to which manuscripts about the research are submitted, and media, lay and professional audiences with whom the research or other activity is discussed orally or in writing).
- Requiring the individual to refrain from participating in certain activities or aspects of activities relating to the research project (e.g., requiring IRB members with conflicts of interest in connection with research protocols to recuse themselves from deliberations on those protocols, or, where compelling circumstances exist to allow certain research stages or activities to proceed despite a conflict of interest, restricting the individual's roles to those stages and activities, including establishing a point in time for stopping participation and strategies to keep the individual's involvement at a minimum).
- Requiring the activity to be approved by additional individuals or entities (e.g. such as deans, department chairs, or program chairs).
- Requiring others to review academic decisions in which the individual participates.
- Requiring the independent involvement of other personnel in the research (e.g. such as in recruiting and selecting subjects, participating in or designing the consent process, providing clinical treatment to subjects apart from the research intervention or procedures, monitoring data, reviewing study design, collecting data, and determining authorship status or order).
- Requiring the individual to reduce, modify, or eliminate a financial interest (including divesting ownership, restricting the sale or exercise of stock and stock options, and deferring or waiving royalties or milestone payments).
- Requiring the individual to vacate a position.
- Prohibiting the individual from disclosing confidential institutional information or channeling discoveries to an outside entity.
- For research projects involving human subjects research, requiring the individual to disclose conflicts of interest to participants.
- Prohibiting the research from taking place at MHS.
- Requiring continued oversight of the activity by the Research Compliance Committee.

# Attachment B

**Duties under 42 CFR § 50.604**

MHS must maintain an up-to-date, written and enforced policy on financial conflicts of interest and make said policy available via a publicly accessible website. MHS must adhere to this policy and provide FCOI reports regarding identified financial conflicts of interest to the PHS Awarding Component in accordance with MHS standards.

MHS must inform each Investigator of this policy, the Investigator's responsibilities regarding disclosure of SFIs, and of the applicable federal regulations. MHS must also require all Investigators to complete training regarding these things prior to the Investigator's engaging in PHS-funded research and, thereafter, at least once every two years.

**Public Notice Requirement Duties under 42 CFR § 50.605(5)**

Within 5 days of receiving a request for information, MHS shall make available via a written response information concerning any financial interest disclosed to MHS that meets the following three criteria: (1) The financial interest was disclosed and is still held by an Investigator who has been identified by the MHS as senior/key personnel for the research project; (2) The Research Compliance Committee determines that the financial interest is related to the research; and (3) The Research Compliance Committee determines that the financial interest is a FCOI.

The information that will be disclosed is:

- Investigator's name
- Investigator's title and role with respect to the research project
- The name of the entity in which the SFI is held
- The nature of the SFI
- The approximate dollar value of the SFI

Information regarding Investigator Conflicts of Interest will remain available for three years from the date of the most recent disclosure or update.

**Duty to Report to NIH Under 42 CFR § 50.605(b) & 42 CFR § 50.606(a)**

Pursuant to 42 CFR § 50.605(b) & 42 CFR § 50.604(h)MHS must send initial, annual, and revised reports on Financial Conflicts of Interest to NIH prior to the expenditure of funds, within 60 days of identification for an Investigator who is new to the project, within 60 days for newly identified Financial Conflicts of Interest for existing Investigators, and otherwise at least annually to provide an update on the status of the Financial Conflicts of Interest and any changes to the management plan. Pursuant to 42 CFR § 50.605(a)(3)(iii), MHS must notify NIH promptly if bias is found with NIH-funded research and must submit a Mitigation Report to NIH for dealing with the instance of bias. When the grantee is Case Western Reserve University, MHS will file all reports to Case Western Reserve University who will then assume all obligations for reporting to NIH.

If the failure of Investigator to comply with this Policy has biased the design, conduct, or reporting of research, MHS must promptly notify the PHS funding component of the corrective action taken or to be taken.

# Attachment C

**Non-Compliance and Violations of the Policy**

If a MetroHealth employee is found to be in violation of this Policy or a current Management Plan, then that individual will be subject to discipline pursuant to corrective actions or other sanctions deemed appropriate by administrative review.

If a non-MetroHealth employee is found to be in violation of this Policy or a current Management Plan, then that individual will be subject to appropriate contractual sanctions pursuant to the contract, including termination of the contract.

If HHS determines that a PHS-funded project of clinical research, whose purpose was to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by Investigator(s) with an actual Conflict of Interest that was not disclosed or managed, MHS must require the Investigator(s) to disclose that Conflict of Interest in each public presentation of the results of the research.

## Attachment D

**Record Keeping**

MHS is required to keep records of all conflict of interest disclosures, the review of, or response to, such disclosures (regardless of whether the disclosure resulted in action) by MHS, and all actions taken by the MHS with respect to each conflicting interest as follows:

a) 42 CFR 50.604(I) Grants and Cooperative Agreements
For at least three years from the date of submission of the final expenditures report to the PHS or, where applicable, from other dates specified in 45 CFR74.53 (b) and 45 CFR 92.42(b) for different situations

b) Industry Sponsored Contracts
For three years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, Subpart 4.7.

# Attachment E

**Sub recipient Requirements**

MHS shall establish, via a written agreement, whether a sub recipient of an MHS grant will follow the FCOI policy of MHS or the FCOI policy of the sub recipient.

If the sub recipient will follow their own FCOI Policy, MHS will obtain verification from the sub recipient that their FCOI policy complies with the regulations. MHS will also require the sub recipient to report identified FCOIs for its Investigators in a time frame that will allow MHS to report those FCOIs to the NIH.