

POLICY

DEPARTMENT: Organizational	TITLE: Individual Conflicts of Interest/Conflicts of Commitment in Research
PAGE: 1 of 9	REPLACES POLICY DATED: 8/1/2012
EFFECTIVE DATE: March 28, 2017	REFERENCE NUMBER: ORG.O-003
APPROVED BY: Executive Team	LOCATION OF CONTROLLED DOCUMENT: Starport

1. PURPOSE

- A. MedStar Health Research Institute (MHRI) is committed to the protection of human research participants, maintaining high standards of objectivity and integrity in research, as well as high standards for ethical business conduct. MHRI also encourages healthy communication and collaboration between MHRI associates and researchers with external organizations, private research entities, and businesses that make medical devices and/or medicines that may benefit MHRI and patients throughout the MedStar Health system.
- B. The MHRI Individual Conflicts of Interest/Conflicts of Commitment in Research Policy (Policy), which is approved by the MHRI Board of Directors (Board), addresses potential research-related Conflicts of Interest (COI) and Conflicts of Commitment (COC) and establishes the procedures for identifying, managing and minimizing actual, potential, and perceived conflicts on the part of associates, researchers and other persons involved in research activities at one or more MedStar Health (MSH) facilities, as well as MHRI as an entity. This Policy is intended to supplement and support compliance with the MedStar Health Conflict of Interests with Industry Policy. To the extent any language in this policy conflicts with any applicable federal, state or local laws, those laws supersede the language contained within this policy.

2. SCOPE

- A. This Policy applies to all MHRI Board members, MHRI associates and researchers affiliated with MHRI, any individual who proposes to conduct research or who is involved in the design, conduct, or oversight of any research at a MSH facility.¹
- B. This Policy applies to all members of MHRI Review Boards and other research oversight committees, including but not limited to any Institutional Review Board, Scientific Review Board, Institutional Animal Care and Use Committee, Institutional Biosafety Committee, and Research Conflict of Interest Committee (collectively referred to as “Boards and Committees”), whether or not they are employees of MHRI or MSH. For additional policies and requirements related to conflicts of oversight responsibilities, please refer to the policies, procedures and/or bylaws or charters of the individual Boards and Committees.
- C. This Policy also applies to any parties involved in the conduct of research not conducted at a MSH facility but that is overseen, through an Institutional Review Board (IRB) Authorization Agreement,

¹ Except that MSH Investigators and/or Georgetown University (GU) Faculty who conduct research at Georgetown University Hospital under a GU IRB-approved protocol, shall be subject to the GU Faculty Handbook policies governing Conflicts of Interest. **However, any such MedStar Health researchers will be additionally subject to the provisions of this policy, to the extent that they are more stringent than those of the GU Faculty Handbook.** Similarly, Investigators who conduct research at a MedStar Facility under their own IRB-approved protocol pursuant to an MHRI-approved IRB Reciprocity Agreement shall be subject to their own Institution’s policy on Conflicts of Interest, as well as the MHRI requirements, when applicable.

cooperative agreement or IRB of record determination, by an MHRI IRB to the extent it is congruent with any conflict of interest procedures contained within the agreement.

- D. Investigators, employees of MHRI as well as all others who will be involved in the design, conduct, reporting or oversight of research conducted at MSH or overseen by an MHRI IRB are expected to avoid any activity, practice, or act that conflicts with the interests of, negatively impacts their commitment to, or poses the potential for bringing into question the objectivity of the research, the safety of research participants or the integrity and reputation of MSH or MHRI. In accordance with this policy and the following procedures, it is expected that all individuals subject to this policy disclose any interest or external commitment that might produce a real or perceived conflict and that they actively seek to eliminate or manage any identified conflicts in a manner consistent with this policy. Conflicts of interest may be financial, professional, or personal in nature.

3. DEFINITIONS

- A. **Competitor** means any person, firm, corporation or other entity which competes for similar grants or contracts as MHRI or offers to sell, provide or supply items or services in MSH and MHRI's service area that are materially the same as the primary services offered by MSH, MHRI, or any of their affiliates. Physicians practicing medicine in MSH and MHRI's service area are not deemed competitors for these purposes.
- B. **Conflict of Commitment (COC)** includes any situation in which an individual undertakes external or private commitments which burden or interfere with the individual's obligations to the Institution.
- C. **Conflict of Interest (COI)** is any situation when an Interested Person, or a Immediate Family Member of the Person, has Financial Interests or other Personal Interests that may compromise (i) his/her scientific integrity or judgment, or performance of fiduciary or job responsibilities to MSH or MHRI; or (ii) the rights or welfare of research participants; or (iii) the delivery of patient care or other services provided by MSH. A Conflict of Interest occurs when an individual is in a position to influence, data, reports or decisions that may result in personal, professional or financial gain for the individual or for a relative as a result of business dealings or other financial arrangements (including Gifts).
- D. **COI Official** means the person designated to administer and manage MHRI's COI program and has the authority to review and resolve COI matters as described herein or to refer the matter to the RCOIC for resolution.
- E. **Conflict of Interest Committee (COIC)** shall have primary Institutional authority for the review and management of reported or identified potential conflicts of interest of Individuals or the Institution on behalf MHRI.
- F. **Individual** is defined as any person involved in research and responsible for the design, data collection, data analysis, conduct, or report of research, regardless of the source of funding
- G. **Immediate Family Members** are the spouse and dependents of an Individual, including step-children and children by adoption, any other person residing in the same household as the investigator who is a dependent of the investigator or of whom the investigator is a dependent.
- H. **Institution** shall mean MedStar Health Research Institute (MHRI), any subsidiary, or organizational subpart.

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- I. **Institutional Review Board (IRB)** shall have the meaning defined by Federal regulations and shall review the management of reported or identified Individual's or Investigator's potential conflicts of interest and may impose additional requirements to ensure the protections of the rights and interests of human research participants.
- J. **Intellectual Property Affected by Outcomes:** The Individual or Immediate Family Member has a financial relationship or interest, including but not limited to holding intellectual property rights (e.g., patent, copyrights and royalties from such rights), whereby the outcome of the study could influence the value of the financial relationship/interest (e.g., royalties under any royalty-sharing agreements involving MHRI).
- K. **Interests in Direct Competitors:** The Individual (or a Immediate Family Member or the Individual and Immediate Family Member in the aggregate) has an equity interest in (e.g., stock, stock options or other ownership interests)² or relationship with a company which has a marketed product, or is in the process of developing a new product, which is, or will be, according to what the Individual knows at the time of review of the protocol at issue, in direct market competition with the product in the protocol under IRB review such that the Individual has a reasonable belief that his equity interest may be significantly affected.
- L. **Interested Persons** include the directors, officers, and management personnel, medical directors (and other designated physician leaders), and Senior Management of MSH and MHRI.
- M. **Investigator(s)** includes the principal investigator (PI) and any other person responsible for the design, conduct, or report of research, regardless of the source of funding.
- N. **Management** means any person who (1) has management or administrative oversight over an area which utilizes outside vendors, (2) deals with persons or entities whose interest may be adverse to or in competition with MSH, or (3) has authority with respect to a budget/disbursement items of a material amount.
- O. **Management Plan** is the formal plan for eliminating or managing a COI or COC as agreed to by the COIC under the procedures herein.
- P. **Outside/External Professional Activity** means a professional activity (see below) conducted in service to an organization or entity other than MSH or MHRI.
- Q. **Personal/Professional Conflicts of Interest** include the following:
 - 1. **Dual Officer or Directorships:** The Individual or Immediate Family Member holds a position as director, officer, partner, trustee, or any other significant/decision making position in the company funding the research.
 - 2. **Gifts, Gratuities, Rewards, Favors, perks, Completion Bonuses:** See MSH Code of Conduct provisions governing gifts.
- R. **Professional Activity** means an activity in which a person utilizes their knowledge, skills or other abilities in the service of another and for which a person receives compensation either monetary or in the form of other tangible benefits.

² Ownership interests arising solely from investment in a company by a mutual, pension or other institutional investment fund over which the Investigator or Immediate Family Member does not have control shall not be considered included as a conflict of interest.

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- S. **Research** is any systematic investigation involving human participants that is designed (in whole or in part) to develop or contribute to generalizable knowledge.
- T. **Research Monitoring Board** is a board, similar in nature, composition, and responsibilities to a data safety monitoring board (DSMB) that independently monitors research to ensure its safety and integrity in a situation where a particular Conflict of Interest warrants such monitoring.
- U. **Significant Financial Interests** include the following:
1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s or Individual’s institutional responsibilities:
 - a. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value; or
 - b. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
 2. **Excluded from Significant Conflicts of Interest:**
 - a. Salaries, royalties, or other remuneration from MSH, MSH affiliates or MHRI
 - b. Equity interests of an individual (including Immediate Family Members) that do not exceed \$5,000 any single entity; and
 - c. Salary, royalties and other payments, which when aggregated for the individual, Immediate Family Member, are not expected to exceed \$5,000 over the preceding or next 12 months.
 - d. Salary, royalties, or other remuneration paid by the Institution to the Investigator/Individual if the Investigator/Individual is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator/Individual does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local

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government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

- V. **Recruitment Incentives:** The Investigator (or an Immediate Family Member) receives a recruitment incentive, (including enrollment bonuses or referral fees) either at the inception of the trial, during the trial progress, or upon conclusion of the trial.
- W. **Travel Disclosure:** Any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator/Individual and not reimbursed to the Investigator/Individual so that the exact monetary value may not be readily available), related to the Investigator's/Individual's institutional responsibilities must be disclosed. Excluded from the disclosure requirement is travel that is reimbursed or sponsored by the following:
 1. a federal, state, or local government agency,
 2. an Institution of higher education as defined at 20 U.S.C. 1001(a),
 3. an academic teaching hospital,
 4. a medical center, or
 5. a research institute that is affiliated with an Institution of higher education.

4. GIFTS AND GRATUITIES

- A. **Gifts:** Receipt by an Interested Person or Immediate Family Member, of any gift, entertainment, unsecured loans or other favors within the past three (3) years from any company or entity that either (i) furnishes goods or services, or which leases or sells real estate or equipment, to MSH; or (ii) competes with MSH in the delivery of health care services valued at greater than \$100.00 per year, unless such remuneration is evaluated and approved by the COIC. The individual also may not accept gift authorship unless remuneration is evaluated and approved by COIC.
- B. **Gifts and Gratuities.** MHRI recognizes that employees may occasionally be offered or given tokens of appreciation by vendors, patients or others who encounter our services. Employees and agents of MHRI will abide by the MSH Code of Conduct provisions governing gifts. Any gifts or gratuities received must be disclosed per this Policy even if such gifts or donated on your behalf to a charitable organization.

5. DISCLOSURE OF CONFLICTS

- A. **Disclosure of Financial Interests.** If any individual or Immediate Family Member obtains a substantial financial interest in, or becomes a director, officer, employee, or agent of, any Study Sponsor, Supplier, Purchaser or Competitor, the employee shall disclose such interest as provided in this Policy.

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B. Conflicting Policies. This Policy is intended to supplement, not supersede, the policies of MSH and its other subsidiaries governing conflicts of interest. Nothing in this policy is intended to contravene or conflict with a MSH or other policy or procedure involving conflicts of interest. Where a MSH policy directly conflicts with this policy, the MSH policy shall prevail. MSH Policies that may be applicable to persons subject to this policy, include but are not limited to:

1. MSH Conflicts of Interest with Industry Policy
2. MSH Business Ethics and Confidentiality Policy
3. MSH Intellectual Property Policy
4. Any MSH Corporate policies governing prohibited certain financial arrangements
5. MSH Code of Conduct

C. Disclosure of Conflicts of Interest: All individuals subject to this Policy must disclose any potential or actual COI (using the tool described above) to the MHRI Designated COI Official (COI Official) and MHRI IRB, in the case of research overseen by an MHRI IRB, in the following instances:

1. If federal grant monies are being sought in order to support research, in accordance with applicable regulations, all those involved in the design, conduct or reporting of research MUST disclose any potential COI to the granting authority at the time of grant application.
2. Similarly, if an Investigator is self-initiating (self-sponsoring/investigator-initiated) FDA overseen research, disclosures in accordance with the FDA regulations at 21 CFR 54, must be made to the FDA.
3. Disclosure must also be made prior to initiating the development, technology transfer and/or licensing process for the results of research supported or conducted at MSH or MHRI.

D. Disclosure Frequency

1. All individuals subject to this Policy must provide disclosure using the approved disclosure method on an annual basis, as well as upon any material change in circumstances previously reported, and disclose any potential or actual Conflicts of Interest to the COI Official who will then follow the appropriate actions based on the COI Official's responsibilities.
2. If after initiation of research, a potential COI is discovered, which was not reasonably known to be apparent upon initiation of research, then upon discovery of potential Investigator conflict of interests, the Investigator must immediately report this to the COI Official so that the matter may be evaluated in accordance with this policy.

E. Review of Disclosures: In addition to potential research Conflicts of Interest that must be reported to the IRB in connection with specific clinical trials, all research related conflicts of interest or potential conflicts of interest will be reviewed annually by the COI Official. In the event that the COI Official deems that a research conflict of interest exists and requires management beyond disclosure, the matter will be referred to the RCOIC.

F. Training Regarding Conflict Situations and this Policy

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MSH and MHRI employees are encouraged to ask questions of their supervisors about this Policy and its application to the performance of their job responsibilities.

Each Investigator must complete training prior to engaging in research related to any PHS-funded grant or contract and at least every four years, and immediately under the designated circumstances:

1. Institutional FCOI policies change in a manner that affects Investigator requirements
2. An Investigator is new to an Institution
3. An Institution finds an Investigator noncompliant with Institution’s FCOI policy or management plan.
4. All those subject to this policy are responsible for familiarizing themselves with their obligations. MHRI will include information about COI and COC in its employee training materials.

G. Review Board Requirements: In accordance with the relevant bylaws, policies or procedures, no member of an MHRI Board or Committee responsible for overseeing research, including but not limited to an Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Scientific Review Board (SRB), Scientific Advisory Board (SAB) or Conflict of Interest Committees (COIC) may participate in the initial or continuing review of research in which they have a COI except to provide information requested by the Board or Committee. Board or Committee minutes will document recusal of members with COI.

H. Records Management: All records, including disclosure forms, will be retained in accordance with the MSH Record Retention policy. MHRI recognizes that some information concerning a COI or COC may be sensitive and confidential, and will strive to be respectful of the privacy of Individuals while still implementing this Policy effectively. MHRI, the COI Official, and the COIC will not disclose such confidential information unless permitted or required by law and/or this Policy.

10. RESPONSIBILITIES

A. The COI Official is responsible for the effective day-to-day management of actual or potential COI, COC and implementation of this Policy. This includes reviewing all disclosures, making determinations on whether a COI or COC exists, requiring that they be eliminated or managed, adopting a management plan as appropriate and overseeing its implementation.

1. Permanent COI Official. The Director of the Office of Research Integrity, or such other person as designated by MHRI is the Designated COI Official and holds the authority to implement and ensure compliance with this policy and any related procedures, and requirements in this role.
2. Review in the COI Official’s Absence. In the absence of the COI Official, the Research COI Committee Chair (or his/her designee) is responsible for reviewing the research activity will perform the functions of the COI Official as needed until the COI is available or until a new COI Official is appointed. All determinations or actions by the chair will be subject to review and potential alteration or mitigation by the COI official upon their return or appointment.

B. Research Conflict of Interest Committee

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The Research Conflict of Interest Committee (RCOIC) is responsible for assisting and overseeing the COI Official in the determination and management of conflicts of interests. The specific roles, responsibilities and governance of the RCOIC are set forth in its Charter. The RCOIC shall be independent from the line of institutional decision-making authority. The RCOIC is specifically empowered to adjudicate and manage any potential individual-level research-related conflicts of interest involving researchers, associates or other MHRI affiliates. In the event that institution-level officials are unresponsive to recommendations of the RCOIC or are themselves involved in a conflict needing management, the RCOIC is empowered to raise its concerns directly to MedStar Health corporate leadership.

Exceptions

N/A

What Constitutes Non-Compliance

Failure to make disclosures as appropriate or non-compliance with any plan imposed to manage any potential or actual COI constitutes non-compliance with this policy.

Consequences of Non-Compliance

Consequences for non-compliance with the requirements of the Policy, may include suspension of IRB approval, loss of ability to do research at MedStar facilities, reporting to Federal Agencies and/or funding sources, removal from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction or initiation of steps leading to possible rank reduction or termination of employment. Any sanctions will be imposed in consultation with, and at the discretion of MSH and MHRI leadership, as appropriate. Violation of this Policy may result in MSH, its subsidiaries, and/or MHRI taking disciplinary action without limitations, up to and including termination of Investigator’s research activities, termination of employment, and/or referral to appropriate disciplinary boards and other governmental authorities. Recommendations for disciplinary action will be made by the COIC to the IRB and or MSH institutional officers as appropriate to the situation.

Related Policies

1. MSH Conflicts of Interest with Industry Policy
2. MSH Business Ethics and Confidentiality Policy
3. MSH Intellectual Property Policy
4. Any MSH Corporate policies governing prohibited certain financial arrangements
5. MSH Code of Conduct

Procedures Related To Policy

1. ORG.O-003.01 Procedures for Reviewing and Managing Individual COI Related to Research

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Legal Reporting Requirements

Significant financial conflicts of interest that are deemed to be related to research funded by the National Institutes of Health will be reported to the agency and are accessible to the public in a manner described in related procedures.

Reference to Laws or Regulations of Outside Bodies

FDA Financial Interest Regulations: 21 CFR Part 54

Federal Regulations on the Protection of Human Subjects: 21 CFR 56 and 45 CFR 46

Public Health Service (PHS) Regulations: 42 CFR Part 50, Subpart F

Applicable MedStar Health Policies

Business Ethics and Confidentiality Policy
Intellectual Property Policy

Attachments

- A. Forms FDA 3454 and 3455
- B. COI Disclosure Questionnaire

Right to Change or Retire Policy

Modifications to this policy may be made through the process outlined in the MHRI Policy on Policies. If a technical change is required in order to remain compliant with either MSH policies or federal regulatory requirements, such changes may be made by the President of MHRI.

Signed

Date



3/28/17

Neil J. Weissman, M.D.
President

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