

DEPARTMENT: Organizational	TITLE: Individual Conflicts of Interests/Conflicts of Commitments in Research
PAGE: 1 of 5	REPLACES POLICY DATED: 5/21/2012
EFFECTIVE DATE: 8/26/19	REFERENCE NUMBER: ORG.O-003
APPROVED BY: Executive Team	LOCATION OF CONTROLLED DOCUMENT: Starport

Purpose

MedStar Health Research Institute (MHRI) is committed to ensuring that research within MedStar Health is conducted with integrity and that the rights of research subjects are protected. The purpose of this policy is to establish guidelines for identifying and managing potential and perceived conflicts of investigators and others involved in the conduct and administration of research. MedStar Health aims to foster and promote collaborative relationships to advance MedStar's mission, vision and values. As a result of this collaboration, actual or perceived conflicts may arise that require disclosure, review and management. This policy and related procedures are intended to supplement MedStar Health's Conflict of Interests and Interactions with Industry Policy and other MedStar Health policies pertinent to integrity and conflicts of interest. To the extent that any language in this policy conflicts with applicable federal, state or local laws, those laws supersede the language contained within this policy.

Scope

This policy applies to all individuals engaged in the conduct of research within MedStar Health and all of its affiliated entities and subsidiaries.¹

This policy also applies to any parties involved in the conduct of research not conducted at a MedStar Health facility but that is overseen, through an Institutional Review Board (IRB) reliance agreement or cooperative agreement, by an MHRI IRB.

Policy

Any individual covered by this policy is expected to conduct their affairs so as to avoid or minimize conflicts of interest. Any individual covered by this policy must complete at least annually a financial disclosure that covers the prior twelve months through the designated system used by MedStar Health, whether or not he or she has financial interests to report. Any individual required to complete a disclosure under this policy must submit an updated disclosure within thirty (30) days of acquiring a new financial interest or within thirty (30) days of any change to a previously reported financial interest. Any individual covered by this policy must ensure a disclosure is made prior to the application for Public Health Service (PHS) funds and/or prior to submitting a research proposal to one of the MHRI review boards or to an external review board that MHRI is relying upon for the regulatory review of that research.

¹ MedStar Health Investigators and/or Georgetown University faculty who conduct research at MedStar Georgetown University Hospital under a protocol administered by the GU IRB, may be subject to the GU policies governing conflicts of interest.

Training Required:

MedStar Health shall inform investigators about applicable federal regulations, this policy and related procedures, and the disclosure process. All individuals covered by this policy must complete conflict of interest training prior to engaging in PHS funded research and at least every three years afterward. Training will also be completed when any of the following occur: the financial conflict of interests in research policy changes, an individual covered by this policy is new to research at MedStar Health, or an individual is found to be noncompliant with the policy or his/her approved management plan. Training shall be completed through the designated online training every three (3) years. All individuals subject to this policy are responsible for familiarizing themselves with their obligations.

Public Accessibility:

Prior to the expenditure of PHS funds, MHRI will publish on its publicly accessible website a notification that the institution will respond to any requestor within five business days of a request, information concerning any significant financial interest that has been identified as a conflict of interest and is related to PHS funded research. The response will include the Investigator's name, title and role in the research, the nature of the significant financial interest and the approximate dollar value reported in a range. The response will note that the information is current as of the date of the response and is subject to updates, at least annually, and within sixty days of the Institution's identification of a new financial conflict of interests. The information concerning financial conflicts of interests in response to written requests will remain available for at least three years from the date that the information was most recently updated.

MHRI will also publish the conflict of interests in research policy on the publicly accessible website.

Reporting to PHS

In the case of PHS funded research, MHRI will report financial conflicts of interests or non-compliance to PHS in accordance with PHS regulations. If funding for research is made available from a prime PHS-awardee, such reports shall be made by the prime awardee prior to the expenditure of any funds and within sixty (60) days of any subsequently identified financial conflict of interest so that the prime awardee may fulfill their reporting obligations to PHS.

Record Retention

In the case of PHS funded research, MHRI will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to PHS or the prime PHS awardee.

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Definitions

Conflict of Commitment (COC) includes any situation in which an employee undertakes external or private commitments which burden or interfere with the individual’s obligations to MedStar

Equity Interest means stock, stock options, warrants, partnership or other ownership interests. Excluded from this definition are equity interests in publicly traded mutual funds or retirement accounts so long as the investigator does not directly control the investment decision made in these vehicles.

Family means any member of the Investigator’s immediate family including spouse or domestic partner, household members, and dependents, including step-children and children by adoption.

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

Remuneration means all salary and wages, consulting fees, honoraria, paid authorship, travel reimbursement, gifts, licensing revenue, and royalties for books, publications or equity interest. Excluded from this definition is salary paid by to the investigator by the institution if the investigator is currently employed or otherwise appointed by the institution.

Research Conflict of Interest Committee is the committee that advises the research conflict of interest official when necessary on courses of action designed to manage, reduce, or eliminate conflicts of interest in research.

Significant financial interest means a financial interest consisting of one or more of the following interests of an investigator or family member that reasonably appears to be related to the Investigator’s institutional responsibility:

1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest as of the date of disclosure, when aggregated, exceeds \$5,000.
2. With regard to a non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity during the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator or family member holds any equity interest in the entity.
3. A significant financial interest includes any intellectual property rights and interests (i.e. patents, copyrights), upon receipt of income related to such rights and interests.

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Excluded from the definition of significant financial interest:

1. Salaries, royalties, or other remuneration paid by MedStar Health or any of its affiliated entities or subsidiaries if the investigator is employed or otherwise appointed by the institution;
2. Income from seminars, lectures, or teaching engagement sponsored by or from advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education, academic teaching hospitals and medical centers;
3. Income from the authorship of academic or scholarly works;
4. Equity interests or income from investment vehicles so long as the investigator does not directly control the investment decisions made in these vehicles

Travel means any travel that is reimbursed or paid for on behalf of the investigator and related to the investigator's institutional responsibilities. Excluded from the disclosure requirement is travel that is reimbursed or sponsored by Federal, state or local governmental agencies, institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals and medical centers.

Responsibilities

1. The Research Compliance Director is responsible for compliance with this policy.
2. The Research Compliance Director or designee serves as the Conflict of Interest Official for Research.
3. The President of MedStar Health Research Institute is responsible for ensuring compliance with this policy prior to application for and/or expenditure of PHS funds.

Exceptions

There are no exceptions to this policy.

What Constitutes Non-Compliance

Any of the following acts and failures constitutes non-compliance with this policy:

1. Failure to make complete and timely disclosures when required,
2. Intentionally or recklessly providing incomplete, erroneous, or misleading information on the disclosure form,
3. Failing to provide requested information needed for the review of potential or actual conflicts of interest in a timely manner, or
4. Failure to adhere to the requirements of any plan imposed to manage, reduce, or eliminate conflicts of interest in research.

Consequences of Non-Compliance

Consequences of non-compliance with this policy may include recommendation to the IRB to suspend approval of research, loss of the ability to do research at MedStar facilities, reporting to

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federal agencies and/or funding sources if required, recommendation for removal from a specific project, special monitoring of future research, or termination of employment.

Legal Reporting Requirements

Non-compliance with this policy may result in reporting non-compliance to sponsors, funding sources and federal agencies.

Reference to Laws or Regulations of Outside Bodies

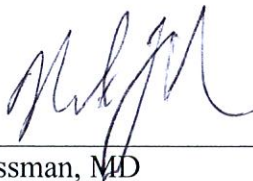
42 CFR 50 Subpart F

45 CFR 94

Right to Change or Retire Policy

Modifications or retirement of this policy may be made at the direction of the Research Compliance Director as necessary to remain in compliance with applicable regulations and MedStar Health policies.

Signed



Date

9/8/2019

Neil J. Weissman, MD

President

MedStar Health Research Institute

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