

DEPARTMENT: Organization	TITLE: Research Conflict of Interest Non Compliance
PAGE: 1 of 3	REPLACES PROCEDURE DATED: N/A
EFFECTIVE DATE: 08/26/2019	REFERENCE NUMBER: ORG.O-003.03
APPROVED BY: Executive Committee	LOCATION OF CONTROLLED DOCUMENT: StarPort

1. PURPOSE

- 1.1. The purpose of this procedure is to establish the process for enforcement of the related policy and procedures and remedies and reporting requirements for noncompliance.
- 1.2. This procedure also outlines the process for appeals of decisions related to sanctions for non-compliance.

2. SCOPE

- 2.1. The procedure applies to all individuals engaged in the conduct of research within MedStar Health and all of its affiliated entities and subsidiaries.¹
- 2.2. The procedure 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) Authorization Agreement, cooperative agreement or IRB of Record determination, by an MedStar Health Research Institute (MHRI) IRB.

3. DEFINITIONS

- 3.1. Non-Compliance means any failure to adhere to the requirements of the Conflict of Interest in Research policy, related procedures or applicable federal, state and local regulations. Non-compliance also means failure to adhere to the requirements of a management plan imposed by the Conflict of Interest (COI) Official for Research or the IRB.

4. RESPONSIBILITIES

- 4.1. The COI Official for Research (or his/her designee) is responsible for monitoring compliance with all applicable policies, procedures and regulations. The COI Official is also responsible for enforcement of the management plans related to conflicts of interest in research. All references to the COI Official for Research in this procedure include his or her designee.
- 4.2. The President of MHRI is responsible for possible sanctions related to failure to disclose potential or actual conflicts of interest or failure to adhere to assigned management plans.

¹ MedStar Health Investigators and/or Georgetown University (GU) 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.

5. PROCEDURE

- 5.1. The COI Official for Research will periodically monitor the adherence to assigned management plans.
- 5.2. If the COI Official for Research discovers a failure to adhere to a management plan, or receives a report of a failure to adhere to a management that after investigation is confirmed, the individual may be subject to sanctions, including suspension of active research.
- 5.3. Any individual covered by the Conflict of Interest in Research policy and related procedures who fails to disclose a potential or actual conflict of interest may be subject to sanctions, including suspension of active research.
- 5.4. The COI Official for Research, upon discovery of a significant financial interest or a potential or actual conflict of interest that was not timely disclosed or was not timely identified while the research is ongoing, will require disclosure from the individual through the designated system and will be responsible for discussing possible sanctions for the failure to disclose the interest with the President of MHRI.
- 5.5. Suggested sanctions from the COI Official for Research will be presented to the President of MHRI. The President will review the suggestion and impose sanctions if deemed appropriate. The COI Official for Research will also review the interest, within 60 days of the disclosure, and determine whether a conflict of interest exists and if so, implement a management plan that shall specify the actions that have been taken, and will be taken, to manage the conflict of interest going forward.
 - 5.3.1. If sanctions are imposed, the COI Official for Research will notify the individual in writing of those sanctions and will notify the individual of the right to appeal the decision.
 - 5.3.1.1. To appeal a decision related to sanctions, the individual should indicate, in writing, the basis of the appeal and provide the appeal to the MHRI President within thirty (30) days of the date of the sanctions decision.
 - 5.3.2. The decision related to sanctions will be forwarded to the reviewing IRB.
 - 5.3.3. MHRI will promptly notify the Public Health Service (PHS) Awarding component, if applicable, of the action taken. If the funding for research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.
- 5.6. In the case of PHS funded research, if a conflict of interest was not identified or managed in a timely manner due to failure by the individual to disclose the interest, failure by the institution to review or manage the interest, or failure by the individual to comply with the imposed management plan, the following steps will be taken:
 - 5.4.1. Within 120 days of the discovery of noncompliance, the COI Official for Research will ensure that a retrospective review of the individual's activities and

2 | Research Conflict of Interest Non Compliance

Version	Review or Change Date	Description of Change	Scheduled Revision Date
1.0	08/26/2019	New Procedure	FY2023

of the research project is completed to determine if any of the research conducted during the period of noncompliance was biased in design, conduct, or reporting of such research.

5.4.2. Based on the results of the retrospective review, if appropriate, MHRI will update the previously submitted conflict of interest report specifying the actions that will be taken to manage the conflict going forward.

5.4.3. If bias is found and the research involves PHS funding, MHRI will notify the PHS Awarding component and submit a mitigation report.

6. RELATED DOCUMENTS

ORG.O-003 *Individual Conflicts of Interests/Conflicts of Commitments in Research Policy*

ORG.O-003.002 *Research Conflict of Interest Disclosure Procedure*

7. REFERENCES

42 CFR 50 Subpart F

Neil J. Weissman, M.D., President
MedStar Health Research Institute

Approver's Name



Approver's Signature

9/8/2019

Date

3 Research Conflict of Interest Non Compliance

Version	Review or Change Date	Description of Change	Scheduled Revision Date
1.0	08/26/2019	New Procedure	FY2023