

DEPARTMENT: Organization	TITLE: Research Conflict of Interest Disclosure
PAGE: 1 of 4	REPLACES PROCEDURE DATED: N/A
EFFECTIVE DATE: 08/26/2019	REFERENCE NUMBER: ORG.O-003.02
APPROVED BY: Executive Committee	LOCATION OF CONTROLLED DOCUMENT: StarPort

1. PURPOSE

- 1.1. The purpose of this procedure is to establish the process for disclosure and review of financial interests and external commitments for individuals engaged in the conduct of research.

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 a MedStar Health Research Institute IRB.

3. RESPONSIBILITIES

- 3.1. All individuals covered by this procedure are responsible for making disclosures as outlined in this procedure.
- 3.2. The Conflict of Interest (COI) Official for Research is responsible for ensuring that the established conflict of interest disclosure and review process is adhered to. The COI Official for Research is also responsible for the creation of management plans and ensuring those involved in the conduct of research adhere to management plans imposed by the COI Official for Research and the IRB. The COI Official for Research may designate his or her responsibilities under this procedure to a designee. All references to COI Official for Research in this procedure also include his or her designee.
- 3.3. The Research Conflict of Interest Committee is responsible for advising the COI Official for Research when requested.

4. PROCEDURE

- 4.1. Any individual who is required to make a disclosure shall do so through the designated disclosure system.
- 4.2. Disclosures are required annually, whether or not the individual has a financial interest to report. The disclosure statement shall include the financial interests of the individual and those of his/her family members. Disclosures and review of

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.

- disclosures must be completed prior to the application for Public Health Service (PHS) funds.
- 4.3. 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.
 - 4.4. The COI Official for Research will review the disclosures when they are made in the designated system.
 - 4.5. If the administrative review of the disclosure reveals that the disclosed financial interests do not represent a significant financial interest, that determination shall be recorded, and no further action will be required.
 - 4.6. If the disclosure represents a significant financial interest and a real or perceived financial conflict of interest appears to exist, the COI Official for Research will draft a management plan for the disclosed interest.
 - 4.7. In drafting the management plan, the COI Official for Research will review the disclosure in light of related research activity. The COI Official for Research may develop and implement a management plan that shall specify the actions that have been, and shall be implemented to manage the real or perceived conflict of interest.
 - 4.7.1 Examples of conditions or restrictions that might be imposed to manage a real or perceived conflict of interest include, but are not limited to:
 - 4.7.1.1. Public disclosure of financial interests during presentations, publications, or other disseminations, whether oral or written;
 - 4.7.1.2. Disclosure of financial interest to prospective subjects and to the research sponsor, whether governmental or private;
 - 4.7.1.3. Monitoring of the research by independent reviewers;
 - 4.7.1.4. Modification of the research plan, research staff roles, or changes in location of certain research activities to address the potential bias from interests;
 - 4.7.1.5. Disqualification from participation in all or a portion of the research;
 - 4.7.1.6. Required periodic reports regarding implementation of the management plan and its progress to oversee and monitor the entire project;
 - 4.7.1.7. Reduction or elimination of the financial interest; or
 - 4.7.1.8. Severance of the relationships that create financial conflicts.
 - 4.8. The COI Official for Research will be responsible for communicating the resolution of the matter to the individual and the IRB.
 - 4.9. Any real or perceived conflict of interest with regard to the individual's current or proposed research must be reviewed by the COI Official for Research prior to final IRB approval. The IRB may impose additional management actions that are more stringent than the terms in the management plan imposed by the COI Official for

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Research. The IRB may not alter the management plan imposed by the COI Official for Research to make the terms less stringent.

4.10. An internal review will be conducted periodically by the COI Official for Research (or his/her designee) to determine compliance with selected management plans. If an individual is found to be non-compliant, then the internal review results will be referred to the Institutional Official for possible sanctions.

4.10.1. Failure of an individual to comply with the approved management plan for the conflict of interest may result in any of all of the following sanctions:

4.10.1.1. Suspension from any or all research activity

4.10.1.2. Termination of any or all research activity

4.11. Prior to expenditure of any PHS funds under an award, the institution will report to the PHS Awarding Component the existence of a conflict of interest in accordance with PHS financial conflict of interest reporting instructions and assure that the conflict of interest has been managed, reduced or eliminated in accordance with 42 CFR 50.605.

4.12. If the COI Official for Research becomes aware of any real or perceived conflict of interest that was not disclosed or identified in a timely manner while research is ongoing, the COI Official for Research will within sixty (60) days of discovery of the financial interest, review it, determine whether a conflict of interest exists and if so, implement a management plan that shall specify the actions that have been, and will be, taken to manage such conflict of interest going forward. The COI Official for Research will follow the process outlined in ORG.O-003.003 *Conflict of Interest Noncompliance Procedure*.

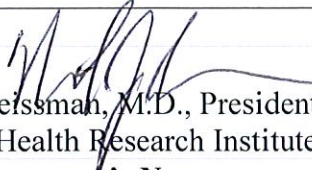
5. RELATED DOCUMENTS

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

ORG.O-003.003 *Conflict of Interest Noncompliance Procedure*

6. REFERENCES

42 CFR 50, Subpart F



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MedStar Health Research Institute

Approver's Name

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MedStar Health
Research Institute

Research Conflict of Interest Disclosure

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Approver's Signature

9/8/2019

Date

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