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| DEPARTMENT: Organization | TITLE: Research Conflict of Interest Committee |
| PAGE: 1 of 2 | REPLACES PROCEDURE DATED: N/A |
| EFFECTIVE DATE: 08/26/2019 | REFERENCE NUMBER: ORG.O-003.01 |
| APPROVED BY: Executive Committee | LOCATION OF CONTROLLED DOCUMENT: StarPort |

1. PURPOSE

- 1.1. The purpose of this procedure is to establish the process for convening the Research Conflict of Interest Committee and the process for the committee's review of disclosures 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. The MedStar Health Research Institute President in consultation with the Conflict of Interest (COI) Official for Research, is responsible for appointing members to the Research Conflict of Interest Committee.
- 3.2. The COI Official for Research (or his or her designee) is responsible for ensuring that the established conflict of interest disclosure and review process is adhered to. The COI Official for Research (or his or her designee) is also responsible for convening the Research Conflict of Interest Committee to review certain disclosures and for administratively managing the committee activities and actions including, but not limited to preparing agendas, taking minutes, and issuing letters from the committee.
- 3.3. The Research Conflict of Interest Committee is responsible for reviewing certain financial interests, as determined by internal criteria, which have been deemed to be an actual or potential conflict of interest. The committee is responsible for considering any actions or conditions required to manage the actual or potential conflict.

4. PROCEDURE

- 4.1. Completed conflict of interest questionnaires for researchers will be reviewed by the COI Official for Research or his/her designee.

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.

- 4.2. The COI Official for Research or his/her designee has the authority to impose a management plan according to internal guidelines set by the COI Official for Research in consultation with the MedStar Office of Corporate Business Integrity and the MedStar Health Research Institute President (herein after referred to as “internal guidelines”).
- 4.3. For certain disclosures that meet criteria established by internal guidelines, the disclosure will be reviewed by the Research Conflict of Interest Committee.
- 4.4. The COI Official for Research or his/her designee will schedule a meeting for committee to discuss the disclosure needing review and management.
- 4.5. The COI Official for Research or his/her designee will prepare meeting materials, including an agenda, suggested management plan for consideration, and meeting minutes.
- 4.6. The Research Conflict of Interest Committee will convene to discuss the disclosure needing review and will consider all applicable federal, state, and local requirements in addition to applicable MedStar Health policies and standards when imposing a management plan for the disclosure.
- 4.7. Once the Research Conflict of Interest Committee approves a management plan for the disclosure being reviewed, the COI Official for Research or his/her designee will finalize the management plan document and obtain the researcher’s agreement and signature.


5. RELATED DOCUMENTS

ORG-O.003 *Individual Conflicts of Interest/Conflicts of Commitments in Research*
 ORG.O.003.02 *Research Conflict of Interest Disclosure*
Conflicts of Interest and Interactions with Industry

6. REFERENCES

45 CFR 50 Subpart F

Neil J. Weissman, M.D., President
 MedStar Health Research Institute
Approver’s Name



Approver’s Signature

9/8/2019
Date

| 2 | Research Conflict of Interest Disclosure | | | |
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| Version | Review or Change Date | Description of Change | Scheduled Revision Date | |
| 1.0 | 08/26/2019 | New Procedure | FY 2023 | |