

SYSTEM POLICY

EC-45 - Objectivity in Research and Conflict of Interest Disclosure

Owner: Ethics and Compliance Department

Key Points

- The MetroHealth System (MHS) values discovery through Research¹ and maintains policies and processes that support integrity in all Research matters, including processes to identify and address Research Conflicts of Interest.²
- This policy describes requirements related to the disclosure and management of Conflicts of Interest involving Workforce Members³ who perform Research at MHS (referred to as Research Workforce Members). This policy applies to both Public Health Services (PHS)⁴-funded and non-PHS funded research.
- This policy does not apply to non-MHS faculty or medical or allied health students, who are covered by their respective institutions' policies.

Policy

1. Related Policies. In addition to this policy, Research Workforce Members reference and follow related MHS policies including:
 - 1.1. [EC-02 - Code of Conduct and Certification](#)
 - 1.2. [EC-08 - Conflicts of Interest](#)
 - 1.3. [EC-10 – Outside Activities](#)
2. Conflict of Interest Training. Ethics and Compliance provides Conflicts of Interest training to all Research Workforce Members at MHS:
 - 2.1. Prior to engaging in Research (as a new MHS Research Workforce Member or part of a new Research study) and every four years thereafter;
 - 2.2. Upon any revisions to this policy that affect investigator requirements; and
 - 2.3. As deemed necessary by the Research Administrative Business Office or Ethics and Compliance, such as in response to noncompliance with this policy.
3. Required Disclosure. Research Workforce Members complete a Conflicts of Interest Disclosure Statement (Disclosure Statement) in the designated electronic system:
 - 3.1. Before engaging in Research at MHS, which means no later than at the time of application for PHS-funded Research or submission of the Research proposal to the MHS Institutional Review Board (IRB) for review;
 - 3.2. Annually; and
 - 3.3. Within 30 days of a material change related to Significant Financial Interests (SFIs).⁵
4. Disclosed SFIs. Research Workforce Members disclose SFIs that they or an Immediate Family⁶ member hold.
 - 4.1. SFIs include:

- 4.1.1. Honoraria or consulting compensation exceeding \$5,000 (cash or non-cash) in the previous twelve (12) months, from a single non-MHS entity, including but not limited to, speaking fees, advising fees, other fees for services, paid authorship, and other compensation;
- 4.1.2. Equity⁷ interest, such as stock, stock options, or other ownership interest;
- 4.1.3. Intellectual Property (IP) rights such as patents, copyrights, IP royalties, and agreements to share in IP rights, upon receipt of income related to such rights and interests;
- 4.1.4. Fiduciary service such as an appointment as an officer, chief medical officer, director, trustee, partner, or governing board member, whether compensated or not for the fiduciary service; and
- 4.1.5. Payments not described in the research contract.
- 4.2. Activities excluded from the definition of an SFI for research purposes are listed below. Note that these activities may be subject to additional limitations under the MHS policies listed above in section 1.
 - 4.2.1. Honoraria or consulting compensation below \$5,000 (cash or non-cash) in the previous twelve (12) months, from a single non-MHS entity;
 - 4.2.2. Income, travel expenses, and/or compensation for service on advisory committees such as a reviewer for a governmental or recognized inter-governmental agencies, academic entities, or professional societies;
 - 4.2.3. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined by 20 U.S.C. 1001(a), or an academic teaching hospital, medical center, or research institute affiliated with MHS;
 - 4.2.4. Income for reviewing scholarly manuscripts for publication by academic journals or presses;
 - 4.2.5. Income from diversified mutual funds or retirement accounts where the individual is not responsible for directing investments; or
 - 4.2.6. Compensation received through an awarded Research grant or a clinical trial agreement administered through MHS.
- 5. Conflicts of Interest Reviews. Ethics and Compliance solicits, receives, tracks, and reviews Disclosure Statements.
 - 5.1. Ethics and Compliance performs a preliminary review on submitted Disclosure Statements and determines whether the Research Workforce Member may continue with the Research pending completion of the full review outlined in sections 5.2-5.3.
 - 5.2. Within sixty (60) days of the disclosure, Ethics and Compliance determines whether any reported SFIs constitute a Conflict of Interest or PHS-Reportable Financial Conflict of Interest.⁸ If an SFI constitutes a Conflict of Interest or PHS-Reportable Financial Conflict of Interest, Ethics and Compliance refers the matter to the Research Conflicts of Interest Committee.
 - 5.3. The Research Conflicts of Interest Committee⁹ reviews identified Conflicts of Interest involving Research Workforce Members.
 - 5.3.1. Ethics and Compliance, in consultation with Legal and the IRB as appropriate, develops a management plan tailored to the specific SFI, and the Research Management plan provisions may vary depending on the presence of an institutional or individual Conflict of Interest and whether the investigator is conducting bench, animal, or human subjects Research.
 - 5.3.2. The Research Conflict of Interest Committee approves a conflicted arrangement subject to a management plan. The management plan requires the design, conduct, and/or reporting of the Research to be free from bias that may result from the Conflict of Interest.

- 5.3.3. The Research Workforce Member signs the management plan and Ethics and Compliance communicates the plan to affected parties.
 - 5.3.4. Ethics and Compliance and the Research Conflicts of Interest Committee monitor compliance with management plans.
- 5.4. Case Western Reserve University (CWRU). For Research conducted at MHS for which CWRU is the grantee institution, Ethics and Compliance collaborates with CWRU to determine which party will own and audit any management plan.
6. Additional Requirements for Human Subjects Research. The Research Conflicts of Interest Committee must find compelling circumstances to justify an investigator's participation in Human Subjects Research when the Conflict of Interest or PHS-Reportable Financial Conflict of Interest results from certain types of SFIs (including intellectual property rights, compensation from the study sponsor, etc.).
7. Failure to Report. If MHS identifies an SFI that a Research Workforce Member failed to disclose timely, Ethics and Compliance does the following within 60 days:
 - 7.1. Reviews the SFI in accordance with sections 5.1-5.4;
 - 7.2. Determines whether it is related to PHS-funded research;
 - 7.3. Assesses whether a Financial Conflict of Interest exists;
 - 7.4. Implements mitigation measures as needed; and
 - 7.5. Notifies the Research Workforce Member's immediate supervisor and Research leadership of the failure to disclose.
8. Public Requests and Responses. For PHS-funded research, MHS ensures public accessibility via a publicly accessible website or by providing a written response to any requestor within five (5) business days of a request for information about any PHS-Reportable Financial Conflict of Interest with respect to MHS-identified senior/key personnel so long as:
 - 8.1. The Research Workforce Member disclosed and still holds the financial interest and MHS identifies the Research Workforce Member as senior/key personnel for the Research project;
 - 8.2. The Research Conflicts of Interest Committee determines that the financial interest is related to the Research; and
 - 8.3. The Research Conflicts of Interest Committee determines that the financial interest is an SFI.
9. Record Availability. MHS retains information related to Investigator Conflicts of Interest for three (3) years from the date of the Investigator's most recent disclosure or update.
10. NIH Reporting. MHS complies with required NIH reporting.
 - 10.1. MHS sends initial, annual, and revised SFI reports to NIH prior to the expenditure of funds:
 - 10.1.1. Within sixty (60) days of identification of SFIs for a new Research Workforce Member;
 - 10.1.2. Within sixty (60) days for newly identified SFIs for existing Research Workforce Members; and
 - 10.1.3. Otherwise at least annually to provide an update on the status of the SFI and any changes to the management plan.
 - 10.2. MHS notifies NIH promptly if bias is found with NIH-funded Research and submits the required documentation (Mitigation Report, etc.) to NIH detailing MHS's response to the instance of bias.
 - 10.3. If CWRU is the grantee, MHS files NIH reports with CWRU, and CWRU assumes NIH reporting obligations.

- 10.4. If the Research Workforce Member's failure to comply with this policy has biased the design, conduct, or reporting of Research, MHS promptly notifies the PHS funding component of the corrective action taken or to be taken.
- 10.5. Exception: Applications for Phase I support under the Small Business Innovation Research and Small Business Technology Transfer programs are not subject to NIH reporting requirements but are still subject to the COI procedures outlined in this policy.¹⁰

References

45 C.F.R. Part 94

42 C.F.R. Part 50

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- ¹ Research (including both PHS-funded and non-PHS funded research) means a systemic investigation, including research development, testing, and evaluation, designed to contribute to generalizable knowledge.
- ² Conflict of Interest means a financial interest or other activity that compromises or impairs an individual's business judgment, delivery of patient care, loyalty to MHS, or ability to perform their responsibilities at MHS.
- ³ Workforce Members include employees, providers, volunteers, trainees, and other persons whose conduct, in the performance of work for MHS, is under the direct control of such entity.
- ⁴ PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
- ⁵ Significant Financial Interests (SFIs) means one or more of the interests identified in section 4 held by a Research Workforce Member (or Immediate Family Member) that reasonably appears to be related to the Research Workforce Member's institutional responsibilities.
- ⁶ Immediate Family Member includes the Research Workforce Members and their spouse, domestic partner, dependent children, and other dependents.
- ⁷ Equity includes interests held directly or indirectly, including stock, stock options, or other ownership interest of any amount in either a publicly traded or non-publicly traded entity with financial interests that would reasonably appear to be affected by the conduct or outcome of research.
- ⁸ Financial Conflict of Interest means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- ⁹ Research Conflicts of Interest Committee includes members from the MHS Research community, Ethics and Compliance Department, Legal Department, and other applicable Workforce Members tasked with reviewing and issuing determinations for potential Research Conflicts of Interest
- ¹⁰ 45 C.F.R. § 94.2.

Dates

Initiated May 2019

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Approved

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MHS Policy Committee