

SYSTEM POLICY

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

Owner: Ethics and Compliance Department

Key Points

- The MetroHealth System (MHS) supports bringing discoveries to society through Research,¹ scholarship and other creative endeavors. To assure integrity in all Research matters, MHS maintains a program that identifies and addresses 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 (collectively “Research Workforce Members”). The 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.
- This policy does not apply to applications for Phase I support under the Small Business Innovation Research and Small Business Technology Transfer programs.⁵

Policy

1. Related Policies. In addition to this Policy, Research Workforce Members cross reference and adhere to related MHS policies, such as:
 - 1.1. [EC-02 - Code of Conduct and Certification](#)
 - 1.2. [EC-08 - Conflicts of Interest](#)
2. Conflict of Interest Training. The Ethics and Compliance Department 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 affects the requirements of investigators; and
 - 2.3. As deemed necessary by the Research Administrative Business Office, the Ethics and Compliance Department, or 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).⁶
4. Disclosed Activities. Research Workforce Members disclose SFIs that they or an Immediate Family⁷ member hold. SFIs include:

- 4.1. Honoraria or consulting compensation exceeding \$5,000 (cash or non-cash) in the previous twelve (12) months, from a single non-MHS entity, including speaking, advising, other fees for services, paid authorship and other compensation;
 - 4.2. Equity⁸ interest such as stock, stock options, or other ownership interest;
 - 4.3. Intellectual Property (IP) rights such as patents, copyrights, IP royalties, and agreements to share in IP rights;
 - 4.4. Fiduciary service such as an appointment as an officer, chief medical officer, director, trustee, partner, or governing board member, whether compensated or not; and,
 - 4.5. Payments not described in the research contract.
 - 4.6. Activities excluded from reporting are:
 - 4.6.1. Income, travel expenses, and/or compensation for service on advisory committees or as a reviewer for a governmental or recognized inter-governmental or academic entities or professional societies;
 - 4.6.2. 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;
 - 4.6.3. Income for reviewing scholarly manuscripts for publication by academic journals or presses;
 - 4.6.4. Income from diversified mutual funds or retirement accounts where the individual is not responsible for directing investments; or
 - 4.6.5. Compensation received through an awarded Research grant or a clinical trial agreement administered through MHS.
5. Conflicts of Interest Reviews. The SVP/Chief Ethics and Compliance Officer (CECO) or designee (collectively referred to as “Ethics and Compliance Department”) solicits, receives, tracks and reviews Disclosure Statements.
- 5.1. The Ethics and Compliance Department performs a preliminary review on submitted Disclosure Statements and determines if 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, the Ethics and Compliance Department determines if any reported SFIs constitute a Conflict of Interest or PHS-Reportable Financial Conflict of Interest.⁹ If an SFI constitutes a Conflict of Interest or PHS-Reportable Financial Conflict of Interest, Ethics and Compliance Department refers the matter to the Research Conflicts of Interest Committee.
 - 5.3. The Research Conflicts of Interest Committee¹⁰ reviews identified Conflicts of Interest involving Research Workforce Members.
 - 5.3.1. Ethics and Compliance Department, in consultation with the Legal Department and IRB as appropriate, develops the management plan according to the nature of the SFI and the Research (e.g., presence of an institutional or individual Conflict of Interest and whether the investigator is conducting bench, animal or human subject Research).
 - 5.3.2. The Research Conflict of Interest Committee approves a conflicted arrangement subject to a management plan, provided 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. Once the Research Workforce Member signs the management plan, the Ethics and Compliance Department communicates the plan to affected parties.
 - 5.3.4. The Ethics and Compliance Department 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, the Ethics and Compliance Department collaborates with CWRU to determine which party will own and audit the necessary management plan.

6. Additional Requirements for Human Subjects Research. The Research Conflicts of Interest Committee must find compelling circumstances, such as are those facts that convince the Research Conflicts of Interest Committee that the Investigator may participate in the human subjects Research despite the Conflict of Interest or PHS-Reportable Financial Conflict of Interest to justify the Investigator's participation in the Research when the Conflict of Interest or PHS-Reportable Financial Conflict of Interest results from certain types of SFIs.
 - 6.1. Failure to Report. If a Research Workforce Member fails to timely disclose an SFI within sixty (60) days, Ethics and Compliance and/or IRB requests the Researcher disclose the SFI and the Ethics and Compliance Department reviews the SFI in accordance with sections 5.1-5.4.
 - 6.2. Public Accessibility. For PHS-funded research, within five (5) business days of a request, the Ethics and Compliance Department provides a written response, containing information about any PHS-Reportable Financial Conflict of Interest with respect to MHS identified senior/key personnel so long as:
 - 6.2.1. 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;
 - 6.2.2. The Research Conflicts of Interest Committee determines that the financial interest is related to the Research; and
 - 6.2.3. The Research Conflicts of Interest Committee determines that the financial interest is an SFI.
 - 6.3. 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.
 - 6.4. NIH Reporting. MHS complies with required NIH reporting.
 - 6.4.1. MHS sends initial, annual, and revised SFI reports to NIH prior to the expenditure of funds, within sixty (60) days of identification SFIs for a new Research Workforce Member, within 60 days for newly identified SFIs for existing Research Workforce Members, and otherwise at least annually to provide an update on the status of the SFI and any changes to the management plan.
 - 6.4.2. MHS notifies NIH promptly if bias is found with NIH-funded Research and submits a Mitigation Report to NIH detailing MHS' response to the instance of bias.
 - 6.4.3. If CWRU is the grantee, MHS files NIH reports with Case Western Reserve University, which assumes NIH reporting obligations.
 - 6.4.4. 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.

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 his or her 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 Per 45 C.F.R. § 94.2.
 - ⁶ Significant Financial Interests (SFIs) means one or more of the following interests listed in section 6.1.1 of a Research Workforce Member (or Immediate Family Member) that reasonably appears to be related to the Research Workforce Member's institutional responsibilities.
 1. Honoraria and consulting compensation exceeding \$5,000 in the previous twelve (12) months from a single non-MHS entity (public or non-public);
 2. Equity exceeding \$5,000;
 3. Intellectual Property (e.g., patents, copyrights);
 4. Payments not described in the Research contract; or
 5. Fiduciary service (e.g., Board memberships):
 - ⁷ Immediate Family Member includes Research Workforce Members and his/her spouse, domestic partner, dependent children and other dependents.
 - ⁸ Equity includes interests held directly or indirectly, including stock, stock option 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.
 - ⁹ Financial Conflict of Interest means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
 - ¹⁰ 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.

Dates

Initiated May 2019

Revised March 2020, June 2021

Approved

Cheryl Wahl - SVP, Chief Ethics and Compliance Officer

MHS Policy Committee