



## Investigator Conflict of Interest in Research

### 1. SCOPE

- 1.1. This policy is applicable to Marshfield Clinic Health System (MCHS) and its investigators who plan to participate in, or are participating in Research, or investigators at other institutions who agree to be subject to this policy.

### 2. DEFINITIONS & EXPLANATIONS OF TERMS

- 2.1. Conflict of Interest (COI) means a significant interest that the Research Conflict of Interest Committee (RCOIC) has determined could (or appear to) directly and significantly affect the design, conduct, or reporting of ongoing or proposed research.
- 2.2. Institution of Higher Education means an institution as defined at 20 USC 1001 (a), an educational institution that meets all of the following:
  - Admits as regular students only persons having a certificate of graduation from a school providing secondary education or the recognized equivalent.
  - Is legally authorized within a state to provide a program of education beyond secondary education.
  - Provides an educational program for which the institution awards a bachelor's degree or provides not less than a 2-year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program.
  - Is a public or other non-profit institution.
  - Is accredited by a nationally recognized accrediting organization.
- 2.3. Institutional Responsibilities means activities that derive or descend from one's professional standing or expertise or activities that are conducted on behalf of Marshfield Clinic Health System.
- 2.4. Investigator means principal investigators, co-investigators, key personnel, staff, collaborators, consultants, and all individuals involved in the design, conduct, or reporting of research, as well as spouses and dependent children of these individuals.
- 2.5. PHS Awarding Component means the organizational unit of the Public Health Service (PHS) that funds the research. Organizational units of PHS are: (1) the Agency for Healthcare Research and Quality (AHRQ); (2) the Agency for Toxic Substances and Disease Registry (ATSDR); (3) the Centers for Disease Control and Prevention (CDC); (4) the Food and Drug Administration (FDA); (5) the Health

Resources and Services Administration (HRSA); (6) the Indian Health Service (IHS); (7) the National Institutes of Health (NIH); and (8) the Substance Abuse and Mental Health Services Administration (SAMHSA).

- 2.6. Public Health Service (PHS) is a component of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority may be delegated, including the National Institutes of Health (NIH).
- 2.7. Sponsored Travel means travel that is paid on behalf of the investigator. Does not include travel reimbursed to or from Marshfield Clinic Health System or Investigator's employer if other than MCHS.
- 2.8. Remuneration means salary and any payment for services (e.g., consulting fees, honoraria, paid authorship) when paid directly to the investigator.
- 2.9. Research means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge.
- 2.10. Research Conflict of Interest Committee means the group charged with confirming or refuting Conflict of Interest determinations made by the Research Compliance Officer. This group is also responsible for creating, approving, and monitoring plans necessary to manage Conflict of Interest in research.
- 2.11. Significant Interest (SI) means any of the following held or received by an investigator (including spouse and dependent children) if related to the individual's *institutional responsibilities* (see exclusions at the end of this definition):
- Equity interest in and remuneration from a publicly-traded entity when the value of the equity interest as of the date of disclosure and the value of any remuneration received from the entity in the twelve months preceding the disclosure, in aggregate, exceeds \$5,000.
  - Any amount of equity interest in a non-publicly-traded entity.
  - Remuneration from a non-publicly-traded entity that, in aggregate, exceeds \$5,000 over the twelve-month period preceding the disclosure.
  - Intellectual property (IP) interests or rights (e.g., patents, copyrights) at the point a decision is made to file for protection of the IP or a proposal is being developed to test the product in animal or human subjects, whichever occurs first.
  - IP rights interests or rights held by another individual or entity when the investigator has received or has the potential to receive income from those interests or rights.
  - Reimbursed or sponsored travel from a single entity that, in aggregate, exceeds \$5,000 over the twelve-month period preceding the disclosure. This does not include travel reimbursed or sponsored by Marshfield Clinic Health System.
  - A formal or informal relationship or involvement with a sponsor of the investigator's Research, or a relationship or involvement with an entity that has a direct or indirect financial interest in the sponsor or otherwise stands to benefit from the results of the Research. Examples include positions on sponsor's advisory board or board of directors, service on a board of a venture capital fund that invests in a sponsor, participation on speaker's bureaus for a sponsor, and service on a sponsor's data safety monitoring board.

• EXCLUSIONS:

- ◇ Compensation for services provided directly to Marshfield Clinic Health System
  - ◇ Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles
  - ◇ Any of the following if from a federal, state, or local government agency; an institution of higher education; an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education:
    - Income from seminars, lectures, or teaching engagements
    - Income from service on advisory committees or review panels
    - Reimbursed or sponsored travel
- 2.12. Significantly means to a degree that could potentially alter the outcome of the research.
- 2.13. Sponsored Travel means travel that is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available (does not include travel sponsored by Marshfield Clinic Health System or investigator's employer if other than Marshfield Clinic Health System).
- 2.14. Transactional Disclosure means a disclosure required by policy at a time other than the annual disclosure and triggered by one of two transactions: (1) acquisition of a new interest; or (2) submission of a new IRB application.

### 3. POLICY BODY

Marshfield Clinic Health System will develop processes to ensure that any significant interests held by investigators do not create unmanaged conflicts with their obligation to design, conduct, and report scientifically sound and ethical research.

- a. This policy incorporates the requirements of Public Health Service's regulation on *Promoting Objectivity in Research* found at 42 CFR 50 Subpart F and 45 CFR 94, National Science Foundation requirements, as well as any other funding agency or accreditation requirements regarding the disclosure, review, management, and reporting of interests. These standards provide reasonable expectation that the design, conduct, and reporting of research will be free from bias due to investigator conflict of interest.

#### 3.2. Prohibited Conflicts

- a. The following activities are intrinsically incompatible with the investigator's obligation to conduct research that is scientifically sound, rigorously ethical,

and safeguards the well-being of the human research subject and are, therefore, prohibited:

- Payment/acceptance of recruitment bonuses or incentives for enrolling or referring patients to research studies, including bonuses for achieving certain levels of accrual by specified dates, unless:
  - The payment is built into sponsor-funding agreements that are intended to cover expenses related to extra recruitment efforts;
  - The payment is commensurate with the work being performed; and
  - Any such payment goes to Marshfield Clinic Health System and not to an individual.
- Payment contingent on particular research results or tied to successful research outcomes.
- Any arrangement or activity otherwise restricted by Marshfield Clinic Health System or its policies or state or federal rules or regulations.

### 3.3. Investigator Responsibilities

#### a. COI Training

- All investigators planning to participate in research must complete training to inform them of Public Health Service (PHS) conflict of interest regulations, Marshfield Clinic Health System policy requirements, and their responsibilities as investigators regarding disclosure of financial and associational interests. This training must be completed:
  - Upon new employment with MCRF;
  - Prior to engaging in research;
  - At least every four years; and
  - Immediately when any of the following circumstances apply:  
(1) Marshfield Clinic Health System revises its Investigator Conflict of Interest in Research policy or procedure in a manner that affects the requirements of investigators; (2) an investigator who plans to apply or participate in research is new to the institution; or (3) an investigator is found to be out of compliance with this policy or a management plan.

#### b. Required Disclosure

- Annual Interests
  - All investigators must disclose SI's annually, within the timeframe set for by the Office of Research Compliance. The annual disclosure will include updated information regarding previously disclosed interests.
  - A current annual disclosure must be on file by the time an application for PHS funding is submitted.
- Transactional Interests
  - All investigators must update their annual disclosure within 30 days of discovering or acquiring a new disclosable interest.

- Principal investigators must certify that they have made the required annual and transactional disclosures, prior to IRB review being initiated.
  - Prior to PHS Funding Submission
    - Investigators must have made an annual disclosure within the current disclosure period and attest that it is current, prior to each submission for PHS funding.
- 3.4. Disclosure Review and COI Initial Determinations
- a. The Research Compliance Officer (RCO) is authorized to evaluate and make the initial determination whether SI's of investigators create a potential COI. Any final determination that a COI exists will be made by the RCOIC.
- 3.5. COI Management
- a. SI's of investigators that are determined to create a COI must be managed to the extent that the SI no longer directly and significantly affects the design, conduct, or reporting of the research. If management to this extent is not possible, the interest must be eliminated.
  - b. Management of investigator COIs will be documented in a formal written management plan from the RCOIC. Management strategies may include, but are not limited to:
    - Disclosure of interests to study participants, others conducting the research, and/or in presentations and publications
    - Limitations on the conflicted investigators involvement in the conduct of the research
    - Modification of the research plan
    - Appointment of an independent monitor or research intermediary capable of taking measures to protect the design, conduct, and reporting of the research
    - Reduction or elimination of the SI
    - Severance of relationships that create a COI
  - c. If an investigator COI is related to research involving human subjects, the IRB has final authority to decide whether the COI and its management plan allow the research to be approved.
- 3.6. Appeals
- a. Determinations that an investigator SI creates a COI may be appealed to Marshfield Clinic Health System's Corporate Compliance Officer.
- 3.7. Management Plan Monitoring
- a. The RCOIC will monitor investigator COI management plan compliance. The RCOIC may delegate monitoring responsibility to the RCO, IRB, or others.
- 3.8. Administrative Sanctions
- a. Investigator failure to complete required training, failure to respond to a request for an annual or transactional disclosure, and/or failure to adhere to a management plan may result in administrative sanctions as deemed

appropriate by the Executive Director, MCRF. Such sanctions could include but are not limited to: additional education, additional monitoring, and restrictions on research privileges.

### 3.9. Additional Institutional Responsibilities Specific to PHS-funded Research

#### a. Office of Sponsored Programs (OSP) Confirmation of Disclosures and Management Plans.

- The OSP will ensure that any senior/key personnel has disclosed significant interests in compliance with institutional policy and procedure, prior to the submission due-date of the institution's proposal for PHS-funded research.
- The OSP will ensure that the review of disclosures as well as the development and implementation of a management plan, if required, occurs prior to expenditure of any funds under PHS-funded research.

#### b. Subrecipients

- MCHS will take reasonable steps to ensure that any subrecipient senior/key personnel comply with *PHS regulation on Promoting Integrity in Research* (42 CFR 50 Subpart F and 45 CFR 94).
- The OSP will incorporate, as part of a written agreement with the subrecipient, terms that establish whether subrecipient must comply with the Investigator Conflicts of Interest in Research policy of Marshfield Clinic Health System or an equivalent policy of the subrecipient's institution.
  - If the subrecipient decides to comply with its own policy, OSP will ensure that the subrecipient certifies, as part of the agreement referenced above, that its policy complies with 42 CFR 50 Subpart F or 45 CFR 94, as applicable. If the subrecipient cannot provide such certification, OSP will ensure that the agreement states that subrecipient senior/key personnel are subject to the relevant policy of Marshfield Clinic Health System.
  - If a decision is made that the subrecipient's senior/key personnel will comply with their own conflict of interest policy, OSP will ensure that the agreement referenced above will specify time period(s) for the subrecipient to report all identified conflicts of interest to Marshfield Clinic Health System. Such time period(s) shall be sufficient to enable Marshfield Clinic Health System to provide timely COI reports as required by PHS regulation and as referenced in the reporting section of this policy.
  - If a decision is made that the subrecipient's senior/key personnel will comply with Marshfield Clinic Health System's policy, OSP will ensure that the agreement referenced above will specify time period(s) for the subrecipient to submit all disclosures of Significant Financial and Associational Interests to Marshfield Clinic Health System. Such time period(s) will be sufficient to enable Marshfield Clinic Health System to comply timely with its review, management, and reporting obligations of PHS regulations and this policy.
- Sponsored Programs will report to the PHS Awarding Component all financial and associational conflicts of interest of all subrecipient senior/key

personnel, as defined in the reporting section of this policy, prior to the expenditure of funds and within 60 days of any subsequently identified COI.

c. Reporting to PHS Awarding Component

- Prior to Marshfield Clinic Health System's (MCHS) expenditure of any funds under a PHS-funded research project, OSP will provide the PHS Awarding Component a report of any senior/key personnel's Significant Financial and Associational Interests found by MCHS or subrecipient institution to create a COI and ensure that MCHS or subrecipient institution has implemented a management plan in accordance with regulation and this policy. Sponsored Programs will provide the report to the Research Compliance Officer for review prior to sending it to the PHS Awarding Component.
- A report will not be submitted to the PHS Awarding Component in cases in which MCHS or subrecipient institution identify a COI and eliminates it prior to the expenditure of funds.
- For any Significant Financial or Associational Interest that Marshfield Clinic or subrecipient institution identifies as conflicting subsequent to MCHS's initial COI report during an ongoing PHS-funded research project (e.g. upon the participation of senior/key personnel who is new to the research project), the Office of Sponsored Programs will provide to the PHS Awarding Component, within 60 days, a COI report regarding the COI, and ensure that MCHS or the subrecipient institution has implemented a management plan in accordance with regulation and this policy.
- Where such COI report involves a Significant Financial or Associational Interest that was not disclosed timely by senior/key personnel, or for whatever reason, was not previously reviewed or managed by MCHS, MCHS or subrecipient institution will also complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the COI or perceived COI was biased in design, conduct, or reporting. If bias is found, the Office of Sponsored Programs will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.
- COI reports will include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial or associational conflict, and to assess the appropriateness of MCHS's management plan. Elements of the COI report will include but not necessarily be limited to the following:
  - Project number (i.e., award or contract number);
  - Project Director/Principal Investigator (PD/PI) or contact PD/PI if a multiple PD/PI model is used;
  - Name of the senior/key personnel with the COI or perceived COI;
  - Name of the entity with which the senior/key personnel has a COI or perceived COI;
  - Nature of the Significant Financial or Associational Interests (e.g., equity, consulting fee, travel reimbursement, honorarium, service on board);

- Value of the interest (dollar ranges are permissible; \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
  - Description of how the interest relates to the PHS-funded research and the basis for MCHS's determination that the interest conflicts with such research; and
  - A description of key elements of the institution's management plan, including: a) role and principal duties of the conflicted senior/key personnel in the research project; b) conditions of the management plan; c) how the management plan is designed to safeguard objectivity in the research project; d) confirmation of the senior/key personnel's agreement to the management plan; e) how the management plan will be monitored to ensure senior/key personnel compliance; and f) other information as needed.
- For any COI or perceived COI previously reported by MCHS with regard to an ongoing PHS-funded research project, the OSP will provide to the PHS Awarding Component an annual COI report that addresses the status of the COI or perceived COI and any changes to the management plan for the duration of the PHS-funded research project.
- The annual report shall specify whether the COI or perceived COI is still being managed or explain why the COI or perceived COI no longer exists.
  - OSP will provide annual COI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

#### 4. ADDITIONAL RESOURCES

##### 4.1. References:

- [42 CFR 50 Subpart F](#)
- [42 CFR 94](#)
- [AAMC Guidance](#)
- [NIH COI FAQs](#)
- [AAHRPP Element I.6.B](#)

##### 4.2. Supporting documents available:

- Marshfield Clinic Health System policy – Conflict of Interest Policy of Marshfield Clinic Health System
- Marshfield Clinic Health System policy – Conflict of Interest Disclosure Policy
- Marshfield Clinic Health System policy – IRB Consideration of Conflict of Interest; Member, Guest Reviewer, and Investigator
- Marshfield Clinic Health System Resource Guide – Investigator Sanctions for Failure to Follow Investigator Conflict of Interest Policy



**5. DOCUMENT HISTORY**

Version No.	Revision Description
1.0	Policy #2346.8 converted to the new Document Control System.

**6. DOCUMENT PROPERTIES**

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POLICY