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Research Conflict of Interest

Policy Number: RCP COC-8217-106

POLICY STATEMENT

A conflict of interest has the potential to affect the design, conduct, or reporting of research; therefore, conflicts of interest should be eliminated when possible or effectively disclosed and managed when they cannot be eliminated. The primary goal of this policy is to prevent conflicts of interest from adversely affecting the protection of research participants, the integrity of the research, and the credibility of the Human Research Protection Program (HRPP).

GUIDELINES

A. Definitions:

1. Research COI is defined as a set of conditions in which judgment concerning a primary interest (e.g., subject's welfare, integrity of the project) may be biased by a secondary interest (e.g., non-financial/personal and/or financial gain). COI may be either individual or institutional. Individuals are defined as investigators (principal, sub-investigator, or co-investigators), grant administrators, sub-recipients, and employees (, pharmacists, etc.) that have a direct and/or significant contribution to the study data. COI exists when individuals have extramural financial relationships with industry sponsors or when their federally funded research is likely to impact the commercial viability of a financial interest they may possess: such as patents, stocks, licensing, technology transfer, investments, and gifts.
2. Research staff involved in the design, conduct or reporting of research are required to complete a COI disclosure.

3. Institutional (Covered Entity, Signatory Official, Human Protections Administrator, Institutional Review Board (IRB) members, etc.) COI, actual or perceived, occurs when financial interests either affect or appear to affect institutional processes, such as the conduct, review or oversight of research (refer to PolicyStat ID 8126993).
4. "Financial Interest of the researcher or research staff" means:
    a. Ownership interest, stock options, or other financial interest related to the research unless it meets four tests:
        - No arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research.
            - Does not exceed $50,000 when aggregated for the immediate family.
            - Publicly traded on a stock exchange.
            - No arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research.
            - Does not exceed 5% interest in any one single entity when aggregated for the immediate family.
    b. Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.

B. Disclosure thresholds:
1. Public Health Service (PHS) funding: Investigators that are applying for, or that receive, PHS funding by means of a grant or cooperative agreement, and who plan to participate in, or who are participating in, PHS-funded research are required to disclose to the designated institutional official (designated Legal representative or Director of Research Integrity) any significant financial interest (SFI) no later than the time of the application for PHS-funded research.
2. Each investigator participating in PHS-funded research is required to submit any SFI within thirty days of discovering or acquiring a new SFI (e.g. through purchase, marriage, or inheritance).
    a. A SFI is considered related to research when the SFI is any financial interest that competes with the organization's or individual's obligation to protect the rights and welfare of research participants, or consists of one or more of the following interests of the Investigator or their immediate family (at minimum includes spouse and each dependent child) that reasonably appears to be related to institutional responsibilities:
        1. With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not

otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, travel reimbursement); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or the Investigator or their immediate family holds any equity interest (e.g., stock, stock option, or other ownership interest); or
3. Intellectual property rights (e.g., patents, copyrights), royalties from such rights, technology transfers, licensing and agreements to share in royalties related to such rights.

b. The term SFI does not include the following types of financial interests:
    1. Salary, royalties, or other remuneration paid by Monument Health to the Investigator if the Investigator is currently employed or otherwise appointed by Monument Health; including intellectual property rights assigned to Monument Health and agreements to share in royalties related to such rights.
    2. Any investigator ownership interest in a for-profit entity or joint venture in which Monument Health also has ownership interest.
    3. Income from investment vehicles, such as mutual funds and retirement accounts.
    4. Income from seminars, lectures, or teaching engagements sponsored by Federal, state or local government agency, or an institution of higher education (as defined at 20 U.S.C. 1001 (a);
    5. Income from service on advisory committees or review panels for Federal, state, or local government agency, or an institution of higher education (as defined at 20 U.S.C. 1001(a).

c. Investigators must also disclose the occurrence of any reimbursed or sponsored travel (i.e. paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities. Sponsored travel shall be limited to educational purposes. Any sponsored travel solely for networking or social purposes is strictly prohibited.
    1. This disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state or local government agency, an Institution of higher education as defined at 20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

2. Disclosure of reimbursed or sponsored travel shall include, at minimum:
    a. the purpose of the trip,
    b. the identity of the sponsor/organizer,
    c. the destination, and
    d. the duration of the trip.
3. Food and Drug Administration (FDA) or industry sponsored funding:
   Financial interests of the researcher or research staff, or their immediate means:
    a. Ownership interest, stock options, or other financial interest related to the research unless it meets four tests:
        - Does not exceed $50,000 when aggregated for the immediate family,
        - Publicly traded on a stock exchange.
        - Does not exceed 5% interest in any one single entity when aggregated for the immediate family.
    b. Compensation related to the research unless it meets two tests:
        - Does not exceed $25,000 in the past year when aggregated for the immediate family.
        - No arrangement has been entered into where the amount of compensation will be affected by the outcome of the research.

C. Education:
    1. Education is required immediately when:
        a. Financial conflict of interest policies are revised in a manner that changes researcher requirements.
        b. A researcher is new to the organization.
        c. A researcher is non-compliant with financial conflict of interest policies and procedures.
    2. COI training on Investigator's responsibilities occurs at the individual research sites and is documented accordingly:
        a. Prior to engaging in research;
        b. A minimum of every four years or with any changes to the process, and
        c. Investigator noncompliance

D. Collecting/Disclosing COI information:

1. Institutional/Individual COI information is collected annually at a minimum to assess business relationships they or their immediate family (at minimum includes spouse and each dependent child), may have to include, but not limited to, financial interests, gifts to the organization when the donor has an interest in the research, investments, or other business relationships (licensing agreements, technology transfers, patents, etc). Parties may also disclose COI directly to the Legal Services or Corporate Responsibility departments at any time.
2. Financial conflicts of interest (FCOI) or non-financial conflicts of interest are assessed by the IRB as a routine part of submissions for initial and continuing review of research. Investigators or others involved in the research study are required to complete the Financial Disclosure section on the electronic IRB application form.

E. Evaluating and Managing Research COI:

1. Any positive response to an investigator's financial relationship assessment on the IRB application form indicates a potential conflict of interest. If not already reviewed, the IRB Chair or designee will forward the disclosure to Legal/Corporate Responsibility for review and determination of whether a management plan is required prior to the approval of the research.
2. IRB members who have a conflict (financial and non-financial) shall not participate in the review of research, unanticipated problems, or noncompliance in which they have a conflict of interest, except to provide information requested by the IRB. They are to be recused before any deliberation and during the vote. They are not to be counted towards a quorum when recused. Member's absence due to a conflict of interest will be documented in the IRB minutes.
3. Within 60 days, the disclosed research COI must be evaluated by the designated parties (Legal Services representative and the Director of Compliance) with a recommended management plan reported to the C&E Committee. The COI and how it's been reduced, managed, or eliminated must all also be reported to the appropriate regulatory agency (e.g. PHS or FDA). The report will convey sufficient information to understand the financial conflict. A retrospective review will be conducted to determine whether the research, or a portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct or reporting of such research.
4. The IRB has final authority to decide whether the conflict and the management of such, allows the research to be approved. The IRB will be notified of the conflict (financial and non-financial) by the designated parties listed above following their review, management plan development (if warranted), and any further C&E Committee recommendations.
5. Failure to file; intentionally filing an incomplete, erroneous, or misleading disclosure form; failing to provide additional information as requested by the C&E Committee; or COI related to PHS-funded research that is not disclosed within 30 days are all considered non-compliance and will be evaluated and managed accordingly by the C&E Committee.

F. Public Accessibility:
For PHS-funded research, MH is required to respond publically either by website or written response within five business days of the request, if any SFI disclosed meets the following criteria:

1. The SFI was disclosed and is still held by the senior/key personnel,
2. The SFI was determined to be related to PHS-funded research, and
3. The SFI is a FCOI.

G. If noncompliance is identified, Corporate Responsibility will perform a retrospective audit within 120 days of the investigator and research activities to determine if there was bias in the design or conduct during the period of noncompliance. If bias is identified, Corporate Responsibility will notify the regulatory agency and submit a mitigation report.

H. Conflict of interest records and all actions taken with respect to each conflicting interest will be maintained for at least three years from the date the final expenditure report is submitted to the funding agency or any audit or legal activities associated with the research, whichever is later. Upon request, records will promptly be made available to HHS.

I. This Research COI policy is available to the public on the public internet website.

RESOURCES

Not applicable.

REFERENCES

A. **Arvin, M., Dorsey, A., Gaich, N., Meade, R., Murtha, F. L., Nosowsky, R., Tenney, J., Troklus, D,, Willenberg K., (2008), Research Compliance Professional's Handbook: The Practical Guide to Building and Maintaining a Clinical Research Compliance & Ethics Program.** Minneapolis, MN: Health Care Compliance Association.

B. Amdur, R., M.D. (2002). **Institutional Review Board Member Handbook.** Sudbury. Massachusetts: Jones and Bartlett.

C. **Regulations and Guidance on the Protection of Human Subjects: Clinical Investigator, IRB and Sponsor Responsibilities.** (April 1, 2009 - March 31, 2010). Philadelphia, PA: Clinical Resources

D. Federal Register, Vol. 76, No. 165, Thursday, August 25, 2011, Rules and Regulations

REGULATIONS / STANDARDS

A. 42 CFR 50

B. 21 CFR 54

C. 45 CFR 46

D. 45 CFR 94

E. 45 CFR 690

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Approval Signatures

Step Description	Approver	Date
	Paulette Davidson: President and Chief Executive Officer	09/2021
	Nancy Klunder: Vice President Corporate Responsibility	09/2021