Chapter: **CORPORATE COMPLIANCE**
Title: **FINANCIAL CONFLICT OF INTEREST POLICY**

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Current Approval Date: 12/10/20

Approved by: BOARD ACTION

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I. ABSTRACT

Macomb County Community Mental Health (MCCMH) is committed to protecting the safety and welfare of participants involved in research, maintaining scientific integrity in basic and clinical research, and stimulating the development of useful knowledge. Principled collaboration between agency researchers and staff, research sponsors and other industry representatives is vital to preserve the public's trust. MCCMH research, when conducted, is under the oversight of several federal bodies, including but not limited to the Food and Drug Administration (FDA), National Institutes of Health (NIH), Substance Abuse and Mental Health Services Administration (SAMHSA), and the Centers for Disease Control (CDC). Both PHS and FDA federal regulations require institutions conducting research to have written policies and procedures to identify and manage any significant financial conflict of interest (COI). The purpose of this policy is to assure compliance with all regulations, describe the process for disclosure of any individual potential financial conflict of interest related to research activities, and the steps taken to manage, reduce or eliminate significant conflicts as they relate to conducting research at Macomb County Community Mental Health.

II. APPLICATION

This policy shall apply to the MCCMH Board, all MCCMH administrative/management staff, all other MCCMH Workforce Members (collectively, "MCCMH Staff"), Designated Collaborating Organizations (DCOs) under the SAMHSA grant, as well as to contract network providers of the MCCMH Board and their workforce members, including but not limited to, their employees, independent contractors, and volunteers (collectively, "Contract Network Providers")

III. POLICY

It is the policy of the MCCMH Board that Individuals responsible for the design, conduct or reporting of research conducted under the auspices of MCCMH must disclose financial or other interests which may be, or appear to be, a conflict of interest. Disclosure requirements are broad and must cover anything related to an individual's responsibilities at MCCMH including but not limited to clinical, administrative, and/or research.

IV. DEFINITIONS

A. Individual Financial Conflict of Research: Any financial interest of a covered individual or their immediate family, or of any foundation or entity controlled or directed by the covered individual or their immediate family which reasonably appears to affect the design, conduct or reporting of MCCMH research. Not all disclosed interests result in a conflict of interest. Disclosures will be reviewed to determine:
1) if the interest is related to the research and
2) whether it results in a financial conflict of interest. Examples of things which may be considered a conflict include but are not limited to:
    - Consulting or serving in any position in the company.
    - Non-monetary gifts, such as travel.
    - Holding of stock, stock options, partnership, or ownership interests.
    - Ownership of intellectual property (i.e., patent or copyright).
    - Potential future personal income from licensing discoveries. Financial conflicts of interests in research do not include:
        - Salary from MCCMH.
        - Interest of any amount in publicly traded, diversified mutual funds.
        - Payments made to MCCMH that are directly related to reasonable costs incurred in the conduct of research
        - Income from seminars, lectures or service on advisory committees or review panels sponsored by government agencies (e.g., NIH Study Sections); institutions of higher education as defined at 20 U.S.C. 1001(a); research institutes that are affiliated with an institution of higher education. Income from these sources does not need to be disclosed.

B. MCCMH Research: For purposes of this policy, MCCMH Research refers to all types of research including but not limited to human, behavioral, social, basic science, or other research activities. This encompasses all laboratory based, translational, clinical and outcomes research conducted at MCCMH or utilizing MCCMH facilities, persons served, staff or data. Any MCCMH research involving human participants requires prior review and approval by the CEO. This includes but is not limited to:
    - Clinical research conducted at MCCMH facilities.
    - Studies based on a medical, clinical, or other record or report initiated at MCCMH.

    Study key personnel are MCCMH employees.

C. Individuals Responsible for Design, Conduct or Reporting: Those directly participating in the research project including but not limited to: designing the research protocol; directing

the research or serving as principal investigator (PI), co-investigator or sub-investigator; screening potential participants for eligibility; enrolling participants; administering informed consent; administering or providing the test article; conducting research assessments; analyzing or reporting research data; or participation in the preparation of abstracts or manuscripts, presentations or other public dissemination of research results. For projects involving human participants, this includes everyone listed as key personnel with the Institutional Review Board (IRB). For federally funded projects this also includes outside independent consultants and collaborators. This does not include clinical staff performing routine clinical care who are not considered to be "engaged in research".

D. Institutional Conflict of Interest: Any financial interest of the institution (e.g., stock holdings, royalties, etc.), or financial or business interests of an individual who makes or participates in committees which make institutional decisions affecting purchasing, research or technology transfer which may result or may be perceived to result in a conflict of interest.
E. Disclosure: The process of reporting relationships or interests in outside organizations.
F. Covered Individuals: Individuals conducting MCCMH research including:
    - Investigators (e.g., PIs, co-investigators, sub-investigators)
    - Key research personnel (e.g., research nurses, coordinators, assistants)
    - Administrators, or
    - MCCMH workforce member who conduct research or who are involved in an intellectual property transfer.
G. Immediate Family Member of Covered Individual: Refers to the covered individuals' spouse or domestic partner; birth, step or adoptive parent, child, sibling, grandparents or in laws.
H. Management Plan for Conflicts of Interest: A plan developed to manage, reduce, or eliminate an identified conflict. This plan will be developed based on the outcome of the conflict-of-interest disclosure review process as described below.

V. DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST:

A. PHS regulations require everyone involved in the design, conduct or reporting of PHS (including NIH) funded research to submit a conflict-of-interest disclosure to the Research Institute at least annually. If a current disclosure is not on file, one must be submitted: 1) at the time of the grant application submission 2) when an individual is assigned to a project 3) within 30 days of developing a new relationship or obtaining a new interest.

B. Individuals must disclose any financial interests, regardless of amount, which reasonably appear to affect the individual's institutional responsibilities to MCCMH, including clinical, academic, administrative, or research. These include, but are not limited to, interests in companies who sponsor, fund, or whose products may be used in any research being conducted or which may be proposed. Disclosure must also include any reimbursed or sponsored travel, including the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

C. In the event a conflict of interest arises during the conduct of the research, when a new relationship is developed or a new interest is obtained, the individual must complete an updated conflict of interest disclosure.

VI. COID REVIEW PROCESS:

A. Review for Grant Applications and PHS Funded Research: When a new grant is being submitted or accepted, or a new federally funded sub-contract is being executed, the key personnel listed for the project will be compared to the list of current annual disclosures on file. Positive disclosures will be identified and pulled for review.

B. Review Process for all Research: Individual(s) designated by MCCMH will be responsible for the initial review of all positive disclosures. Questions regarding a disclosure will be directed to the disclosing individual unless otherwise initiated or directed by the disclosing individual. The reviewer will determine whether a disclosure: 1) is related to any current or proposed research, and 2) represents a financial conflict of interest based on one or more of the following:
   a. Any equity interest which directly affects, or could reasonably appear to affect, the research being reviewed, funded, or proposed for funding. This includes investments in a study sponsor or its parent company (if a publicly or non-publicly traded company is involved), such as ownership interest or stock options.
   b. Payments from a study sponsor, its parent company or subsidiary, or the producer/distributor of the product being tested, which in total exceeds $5,000 in the prior year or is expected to in the next year. This includes all types of income including consulting fees, honoraria (including from a third party if original source is the study sponsor), gifts or payment for consulting, lecturing, travel, or service on an advisory board.
   c. Financial arrangements where the value of the compensation could be influenced by the outcome of the study. Examples include:
      - Compensation explicitly for a favorable outcome.
      - Equity interest in the sponsor.
      - Royalty rights.
      - Holding or the promise of a fiduciary role with the sponsor.
      - Any payment in connection to research that is not specified in the Research Agreement between the sponsor and the institution.
      - A proprietary or financial interest in a test product such as a patent, trademark, copyright, or licensing agreement.
      - Serving as an officer, director, employee or functioning in any other fiduciary role for a sponsor, sponsor parent company or sponsor subsidiary, regardless of whether compensation for the service is provided.

   If a conflict exists, MCCMH will determine whether the conflict can be managed to eliminate the introduction of bias to the research and if so, take steps to manage, reduce or eliminate the conflict.

VII. MANAGEMENT PLANS:

A. If it is determined there may be a conflict of interest or the appearance of a conflict, the reviewer, at the direction of MCCMH, will prepare a Management Plan (MP) recommendation. The MP will be designed to address the conflict specific to the individual's role in the study and will reflect the extent of the potential conflict and the level of risk to any human participants. Management Plan requirements may include, but are not limited to:

- A disclosure of the income, relationship or interest in the Informed Consent and Authorization document so prospective participants may make an informed decision about participation in the study.
- A disclosure of the income, relationship, or interest in public releases of information about the study (e.g., advertising, press releases, abstracts, presentations, publications).
- Limits on the conflicted individual's role in the study (e.g., may not serve as principal investigator, may not be involved in administering informed consent, may not analyze data, etc.).
- Independent reviewers, either institutional (internal) or external.
- Designation of a co-investigator without a COI and not in a subordinate role to the conflicted individual.
- Placement of his/her investment in escrow for the duration of the study, and for a suitable period after the completion of the research.
- Divestiture of the financial interest.
- Severance of the relationship(s) with the sponsor or competitor, which caused the conflict or perceived conflict.
- Disqualification of the covered individual from conducting the research in part or in its entirety.
- Oversight by a non-conflicted individual.
- Study audits (e.g., person served eligibility, data integrity).
- Non-approval of the study at MCCMH

Upon approval of the MP by the MCCMH board, the reviewer will send the recommended MP to the appropriate oversight committee or CEO. An oversight committee may not remove any recommendations made by the MCCMH board; however, the oversight committee may add additional safeguards they deem appropriate. For research involving human participants, the MCCMH Board has the final authority to determine whether the research may be approved, given the interests disclosed and the MP developed to manage those interests.

B. Processing Management Plans: The reviewer will follow guidance provided by the MCCMH Board for the project in completing the review and developing the recommended MP. The department lead(s) conducting the research will prepare the final MP and sign it. The conflicted individual will sign it as well and then submit it to the CEO for approval. Upon approval of the fully signed MP, the research may be approved. The MP will be placed on file with MCCMH.

C. Approval of Research: Individuals with a conflict of interest may not provide signature approval for grant applications, project submissions, significant amendments to a project, or

management plans (i.e., department chairs, clinical research managers). Signatures must be obtained from the individual directly above the conflicted individual based on the applicable organizational chart.

VIII. NOTIFICATION TO PHS:

Consistent with the regulations, if it is determined a significant financial conflict of interest exists related to a PHS funded project, the conflict and MP details will be reported to PHS when the MP is instituted and annually thereafter. If MCCMH is participating as a sub-contractee, MCCMH will report the required information to the sub-contractor for subsequent reporting to PHS

IX. NON-COMPLIANCE AND CORRECTIVE ACTION:

A. Failure to disclose a financial COI or non-compliance with a MP will result in corrective action, as determined by the MCCMH Board and/or regulatory agencies. Corrective action may include, but is not limited to:
   - Completion of additional research education as determined by the oversight committee, Research Administration or PHS.
   - Restrictions on the use of data derived from the research.
   - Suspension or termination of the research project.
   - Withdrawal of funding.
   - Formal corrective action.
   - Report of actions to external regulatory agencies.

B. When non-compliance with a COI management plan related to a PHS funded project occurs, a retrospective review will be conducted. If bias in the research is found, a mitigation report will be filed with PHS and include:
   - Key elements documented in the retrospective review.
   - A description of the bias identified in the research.
   - The plan of action(s) to eliminate or mitigate the effect of the bias.

X. MONITORING AND AUDITING:

The Quality Department will conduct periodic audits of research records to assure compliance with each MP. Audit results will be provided to study lead.

XI. EDUCATION AND TRAINING:

A. All individuals responsible for the conduct of research must be knowledgeable about this policy. Conflict of interest policies and procedures will be reviewed with new staff as part of the required Clinical Research Orientation sessions. Additionally, researchers are required to review this policy as part of the annual research compliance training. Education regarding changes or new procedures will be communicated and incorporated into the annual training module. Education will be required immediately when:
   - Financial conflict of interest policies are revised in a manner that changes researcher requirements.
   - A researcher is new to MCCMH.

- A researcher is non-compliant with financial conflict of interest policies and procedures, including a violation of a MP involving PHS funded research.

B. Consistent with federal regulations, researchers involved in PHS funded research will be required to complete a training course specific to PHS requirements. The training must be completed prior to engaging in PHS funded research and at least every four (4) years thereafter.

XII. PUBLIC ACCESS TO COI INFORMATION:

As required by regulation, this policy will be made available to the public on MCCMH's website. Additionally, within five (5) days of a request, information on conflicts of interest for individuals involved in PHS funded research will be provided.

XIII. RECORD RETENTION:

Consistent with MCCMH Record Retention policies, all records relating to conflict-of-interest disclosures, review, and management plans will be retained a minimum of 10 years past the completion of the research.

XIV. INQUIRIES:

Inquiries to this policy may be directed to Corporate Compliance Committee.

XV. LEGAL AUTHORITY/REFERENCES:

42 CFR § 50.604

XVI. EXHIBITS

None