MCCMH MCO POLICY 2-025

Chapter: **CLINICAL PRACTICE**
Title: **CLINICAL PRACTICE AND RESEARCH COMMITTEE**

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Current Approval Date: 04/14/2022

Proposed by: _____ 04/14/2022
Chief Executive Officer Date

Approved by: Al Lorenzo 04/14/2022
County Executive Office Date

I. ABSTRACT

This policy establishes the standards and procedures of Macomb County Community Mental Health (MCCMH), an official agency of the County of Macomb, for the implementation and operation of the Clinical Practice and Research Committee.

II. APPLICATION

This policy shall apply to all directly-operated and contract network providers of MCCMH and any individual, group or organization that desires to provide clinical services or conduct research, investigative activities or utilize experimental intervention methods or medications using MCCMH resources or involving individuals served by MCCMH.

III. POLICY

It is the policy of MCCMH to establish and maintain a Clinical Practice and Research Committee (C & R Committee) that facilitates the provision of a clinical support and guidance program for clinical staff and reviews and evaluates the merits and effects of a research proposal, investigative activity, clinical trial or an experimental intervention or medication. The Committee shall provide recommendations to the MCCMH Chief Executive Officer, who shall have final decision-making authority.

IV. DEFINITIONS

A. Confidential Information

Information included in the clinical record of an individual served, and information acquired while providing mental health services to an individual, that includes, but is not limited to:

1. Information from diagnostic interviews or examinations;

2. Test results and interpretations ordered by mental health professionals or given by a facility;

3. Entries and progress notes from mental health professionals and support professionals; and

4. Information collected and acquired as part of a research protocol.

B. Program Evaluation

A systematic method for collecting, analyzing and using data to examine the effectiveness and efficiency of programs and to contribute to continuous program improvement.

C. History of Prior Approvals/Denials

A listing of all other formal committees or approval bodies which have reviewed and given approval or denial of a research project.

D. Human Subject

A living individual about whom an investigator (professional or student) conducting research obtains data or identifiable private information through intervention or interaction with the individual.

E. Institutional Review Board (IRB)

An appropriately constituted group, registered with the Department of Health and Human Services and designated under an assurance of compliance approved for federal wide use by the Office for Human Research Protections under 45 CFR §46.103(a), that conducts research, oversees the safety of human subjects participating in research and ensures that subjects are adequately informed about the purpose, procedures, activities, risks and benefits of the research.

1. A particular activity needs IRB review when:

   a. The activity involves the systematic collection/analysis of data, from or about living human participants, with the intent to generate new knowledge. This can involve an intervention or interaction with participants; the collection, release or access to identifiable confidential information; or biological specimens from or about participants.

   b. The research involves living human participants, if the research is conducted, supported or otherwise subject to regulation by any federal or state department or agency.

2. Exempt research activities may include activities in which the only involvement of living human participants will be:

   a. Research involving the use of educational tests (cognitive, diagnostic, aptitude,

achievement), survey procedures, interview procedures or observation of public behavior; or

b. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to them.

F. Minimal Risk

The probability and magnitude of harm or discomfort anticipated in the research is not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

G. Principal Investigator

The individual primarily responsible for the design, implementation and evaluation of a proposed research project.

H. MCCMH Project Coordinator

A representative from the MCCMH Clinical Department responsible for the oversight, monitoring and reporting of an approved research project. The Project Coordinator acts as a liaison between the principal investigator and the Clinical Practice and Research Committee.

I. Publication

Public communication of research conducted at or by MCCMH through principal investigators, or data collected or utilized by MCCMH or an MCCMH directly-operated or contract agency. Publication is made by oral, written or electronic means.

J. Research

A formal, systematic investigation directed toward the biological, psychological and social study of a participant or his/her surroundings for the purposes of generating new knowledge and/or confirming previous investigations' bearing upon the etiology, prevention, diagnosis, treatment or management of mental health conditions. The definition of research applies only to primary data collection (i.e., information directly obtained from participants, their relatives or legally authorized guardians.)

K. Evaluation Research

Systematic investigation into the nature and process of evaluation, including methods, practices and utilization of results.

V. STANDARDS

A. Membership Composition and Participation

1. There shall be a core group of four (4) C & R Committee voting members with varying backgrounds and appropriate professional competencies necessary to conduct the committee's functions. The Committee shall have a representative from the:

   a. MCCMH Chief Medical Officer, or designee,

   b. MCCMH Recipient Rights Office,

   c. MCCMH Clinical Department, and

   d. MCCMH Substance Use Department.

2. The C & R Committee, as needed, may request evaluation consultants from knowledgeable professionals within the MCCMH Administrative Office, the Board or the community to assess the feasibility of a research proposal. These individuals may not vote with the C & R Committee.

3. A Chairperson shall be elected by the Committee for a term of two (2) years. The Chairperson may request to be removed; at which time, the remaining members of the Committee shall elect another individual to fill the position.

4. Each C & R Committee member shall sign an "Acknowledgment of Confidentiality" at his/her first Committee meeting which shall be maintained in the Committee's files in the administrative offices of MCCMH.

5. C & R Committee members shall not have any direct association with nor a vested interest in the proposal under consideration. If a permanent member submits a proposal for review, that person shall not participate in the review. The remaining members may select an alternative, knowledgeable person.

6. The C & R Committee shall meet at least quarterly.

B. Development and Educational Training

1. The C&R Committee shall ensure that affiliation agreements with accredited institutions and/or independent consultants, as applicable, are in place to facilitate and provide a program of clinical support related to mental health and substance use disorders for clinical staff in the MCCMH direct and contract provider network.

2. The C & R Committee shall identify clinical and/or research programs that meet the needs of individuals served and the staffing realities of MCCMH.

3. The C & R Committee shall assess the provision of clinical services. This may include but is

not limited to tracking, monitoring, reviewing and requesting evaluations from the participants and/or providers.

C. Review of Research

1. The C & R Committee shall review and provide recommendations to approve, disapprove and/or modify research proposals submitted by investigators wishing to implement a research project at MCCMH directly-operated or contracted network provider sites. The C & R Committee shall:

   a. Ensure that the proposed research is of scientific merit and is based on sound methodology.

   b. Monitor the conduct of research, investigative activity or use of experimental intervention methods or medications which have been approved for adherence to agency standards or relevant policies.

   c. Authorize and review the written research publication prior to its release. The use of any MCCMH data in contradiction of the policies and procedures set forth herein shall be considered an actionable infringement of its rights.

   d. Assist individuals interested in conducting research projects at MCCMH or its directly operated and contract providers and freely distribute this policy to any individual, group or organization who wishes to submit a research proposal to the C & R Committee.

2. When research or an activity requires IRB approval, the C & R Committee shall not review it until IRB approval has been obtained.

3. C & R Committee review shall be mandatory. A review by another entity (e.g., the MDHHS IRB or University affiliated IRBs) shall not waive the required review by the C & R Committee.

4. The C & R Committee shall ensure the rights, benefits and privileges guaranteed by law and applicable regulations or policies for participants in research, investigative activities, clinical trials or the utilization of experimental intervention methods or medications. The C & R Committee shall:

   a. Determine that the benefits of proposed research can be expected to outweigh the risks to human subjects.

   b. Review and approve the process for obtaining informed consent from the subjects of the research and ensure that all participating subjects have given properly signed informed consent, consistent with applicable laws and policies, including 45 CFR Part 46.

5. The C & R Committee shall review externally conducted program evaluation research for new or existing services where the following conditions exist:

   a. Data collection that involves interviews or surveys to collect information about an individual other than an individual served or guardian;

b. A component that will make comparisons between individuals served by MCCMH in the new project and other groups of individuals served by MCCMH; and

c. Experimental manipulation of access to, extent of, or type of services (e.g., random assignment to different levels of service).

6. The C & R Committee shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the C & R Committee's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the C & R Committee's action and shall be reported promptly to the principal investigator, the MCCMH project coordinator, appropriate MCCMH personnel, the MCCMH Chief Executive Officer and participants.

7. Proposals submitted for review that are of insufficient clarity or lack details necessary for a fair and complete review will be returned to the requesting entity without C & R Committee review.

8. The C & R Committee shall develop and adhere to a Research Review Manual, incorporated by reference herein, which includes:

a. Criteria for acceptable research,

b. Proposal requirements,

c. Procedural guidelines, and

d. Sample forms and checklists needed to carry out the functions of this policy.

The C & R Committee shall review and revise the Research Review Manual on a regular basis.

D. Waiver or Deviation from Policy Provisions

1. In making recommendations to proceed with a research project or educational training, the C & R Committee may waive or deviate from select provisions of the policy with sufficient written rationale and justification for each affected provision submitted to the Chief Executive Officer (CEO) along with its recommendation. The CEO's decision shall be final.

2. Any waiver or deviation from the policy's provisions shall not compromise the confidentiality and safety protections provided in the policy.

VI. PROCEDURES

A. Procedures for the facilitation and provision of a clinical support and guidance program for clinical staff in the MCCMH direct and contract provider network include the following:

1. The C & R Committee will evaluate whether a request for clinical support is consistent with the professional disciplines within the MCCMH service system, and with the goals and

priorities of MCCMH.

2. The C & R Committee will secure a memorandum of understanding with appropriate institutions and/or independent consultants supplying clinical support who meet the needs, goals and priorities of MCCMH.

3. The monitoring, review, assessment and evaluation of the clinical experience shall be centralized within the MCCMH Clinical Department.

4. The Clinical Department staff shall report findings from its monitoring and review activities, assessments, and evaluations to the C & R Committee on a periodic basis. The C & R Committee shall determine the need for continued affiliations based on the information presented and the needs identified.

B. Procedures for recommendation to the MCCMH Chief Executive Officer as to the approval or disapproval of proposed research, investigative activities, clinical trials, use of experimental intervention methods or medication, based upon the C & R Committee's review and evaluation, shall be found in the Research Review Manual, incorporated by reference herein.

VII. REFERENCES / LEGAL AUTHORITY

A. 45 CFR Part 46, Protection of Human Subjects

B. 45 CFR Part 164, Sections 508 (Authorization of disclosure of PHI for research study) and 512(i) (Uses and disclosures for research purposes)

C. MCL 330.1116 (2)(i)

D. MCL 330.1724 (2)(a), (b), (c)

E. MCL 330.1748(7)(b)

F. MCL 330.1919

G. MCL 330.1752(b), (f), (j), (k), (m)

H. Commission on Accreditation of Rehabilitation Facilities (CARF) 2020 Standards Manual, 1.K. Rights of Persons Served.

I. MCO Policy 1-001, "Overview: Compliance Program/ Code of Ethics"

J. MCO Policy 6-001, "Release of Confidential Information- General"

K. MCO Policy 6-002, "Release of Confidential Information- Alcohol and Drug Use"

L. MCO Policy 6-005, "Notice of Confidential Information"

M. MCO Policy 6-100, "Notice of Privacy Practices"

N. MCO Chapter 9 Recipient Rights Policies

VIII. EXHIBITS

Macomb County Community Mental Health Research Review Manual