MACOMB COUNTY COMMUNITY MENTAL HEALTH
RESEARCH PROJECT ACKNOWLEDGMENT OF CONFIDENTIALITY

Clinical Practice and Research Committee Members

In the process of serving on the Macomb County Community Mental Health Clinical Practice and Research Committee, I understand that confidential information shall be disclosed to me, and that I am obligated to maintain the confidentiality of this information at all times in keeping with the provisions of the Michigan Mental Health and Public Health Codes, the Code of Federal Regulations governing substance abuse, or any other federal or state laws. I further understand that any violation of the confidentiality of this information may result in removal from the Clinical Practice and Research Committee and the application of other policies and laws as appropriate.

C & R Committee Member's Signature _____ Date _____

Witness _____ Date _____

MACOMB COUNTY COMMUNITY MENTAL HEALTH
Clinical Practice and Research Committee

RESEARCH REVIEW MANUAL

MACOMB COUNTY COMMUNITY MENTAL HEALTH
Clinical Practice and Research Committee

I. Criteria / Acceptable Research

A. Criteria

The Clinical Practice and Research Committee, in recommending the approval or disapproval of a research proposal, shall use the following criteria:

1. Adequacy of the research design;

2. Importance of the research problem;

3. Professional credentials and qualifications of the Principal Investigator and assistants;

4. Completeness of the proposal, especially those sections dealing with methodology and procedures;

5. Conformance of the proposed methodology and procedures with:

   a. Federal laws/rules;

   b. State statutes, MDHHS guidelines and administrative rules;

   c. MCCMH policies; and

   d. Accepted ethical standards.

6. Health, safety, and welfare of the individual(s) served involved as participants in the research;

7. Appropriateness and adequacy of the methods used to obtain informed consent;

8. Possible risks or disruptive effects for the participants, MCCMH, the directly-operated and contract network providers, and the community as a whole;

9. Benefits of the project to the individuals served, other participants, as well as long-term benefits that would accrue in the field of mental health research;

10. Procedures for detecting and responding to any potentially harmful effects that may occur during the course of carrying out the project;

11. Adequacy of resources including suitability of the facilities and availability of equipment, personnel, or other research materials, and other administrative issues; and

12. Roles that the directly operated or contract network provider staff and individual(s) served who act as participants are to perform in the research project.

B. Types of Acceptable Research

Research which may be acceptable at a MCCMH directly-operated or contract network provider includes that which:

1. Is related to the etiology, diagnosis and treatment, or prevention or management of health conditions, developmental disabilities, and/or substance use disorders;

2. Has some potential utility for MCCMH and the mental health field; and

3. Advances knowledge and understanding of mental health conditions or development in a significant way.

II. Proposal Requirements

A. General

1. Each project shall have a designated MCCMH Project Coordinator.

2. Each project shall have a Principal Investigator.

3. Projects shall have full financial disclosure, including in-kind support and matching arrangements.

4. Projects shall define roles that the directly operated or contract network provider staff and participants are to perform.

5. For research involving more than minimal risk, an explanation shall be stated as to whether compensation and/or medical treatment will be available if injury occurs, and if so, of what this will consist, or where further information may be obtained.

6. An explanation shall be included regarding whom to contact for answers to pertinent questions about the research and the research participants' rights, or in the event of research-related injury to the participants, a statement that all such inquiries shall be answered.

B. Informed Consent -- Information to Participants (Principal Investigator)

1. The Principal Investigator shall seek consent only under circumstances that provide the prospective participant or the prospective participant’s legally authorized representative sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence.

2. The Principal Investigator shall supply to all those who are asked to participate in a research project the following, presented in a language understandable to the participant or the representative:

a. A statement that the study involves research, an explanation of the research, the procedures to be followed, the expected duration of the procedures, and identification of procedures which are experimental.

b. A description of any reasonably foreseeable risks or discomforts to the participants.

c. A description of any benefits to the participants or to others which may reasonably be expected from the research.

d. A disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the participants.

e. A statement describing the extent to which confidentiality of records identifying the participant will be maintained.

f. A statement that participation is voluntary; that refusal to participate or the termination of participation prior to completion of proposed procedures will not involve a penalty or loss of benefits to which the participant is otherwise entitled.

3. Additionally, when appropriate, one or more of the following shall be provided to each participant:

a. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable.

b. A statement that significant new findings developed during the course of the research, which may relate to the participant's willingness to continue participation, will be provided to the participant.

c. A statement of any additional costs to the participant which may result from participation in the research.

d. The approximate number of participants involved in the study.

e. Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.

f. The consequences of a participant’s decision to withdraw from the research and procedures for the orderly termination of participation by the participant.

4. Principal Investigators, to ensure comprehension, shall encourage prospective participants and representatives of prospective participants to ask questions about anything they do not understand, and to repeat back what was covered, as necessary. (See MCCMH MCO Policy 9-600, “Informed Consent for Service.”)

C. Informed Consent – Documentation and Review (C & R Committee)

1. Informed consent shall be documented by the use of a written consent form approved by the Clinical Practice and research Committee (C & R Committee) and signed by the participant or the participant’s legally authorized representative. A copy shall be given to the person signing the form. Projects may use the sample MCCMH Informed Consent for Research Projects form, Exhibit D, attached.

2. The research project shall maintain the signed original informed consent form. A copy of the informed consent form shall be maintained in the C & R Committee's file located in the administrative offices of MCCMH.

3. The C & R Committee may choose not to permit an individual(s) served to participate in a research study in some circumstances, such as where there is a question of the individual(s) not possessing adequate comprehension or memory of informed consent materials, where participation might exacerbate the individual(s) served mental state / symptoms, where there is a question as to circumstances surrounding the securing of informed consent by the Principal Investigator, questions as to the adequacy of the information provided to the individual(s) served by the Principal Investigator, or other relevant concerns.

D. Prior Review

1. The Principal Investigator shall provide the C & R Committee with a satisfactory written statement that an established IRB has reviewed the research protocol and determined that:

   a. The rights and welfare of individuals served shall be adequately protected (e.g., description of how all participating individuals served have given proper signed informed consent consistent with applicable laws and policies, including 45 CFR Part 46.); and

   b. The risks in pursuing the proposed research are outweighed by the expected benefits to the participating individuals served. E. Responsibility at Completion – Alleviation of Stress

      Upon completion of the research procedures, the Principal Investigator shall attempt to alleviate, to the extent possible, any confusion, misinformation, stress, physical discomfort, or other

harmful consequences that may have arisen with respect to the participants as a result of the procedures. The Principal Investigator shall ensure that the participants' physical and emotional states are stable at the time of the participants' departure from the research site.

E. Confidentiality

All projects shall address standards for confidentiality as set forth below:

1. The Principal Investigator shall sign an "Acknowledgment of Confidentiality -- Principal Investigators," Exhibit E, attached, as part of the research proposal application package.

2. The research projects records (written, audio/videotaped, photographic) shall be maintained in a secure room, locked file cabinet, safe, or similar container when not in use.

3. The Principal Investigator may disclose an individual's served identifying information only back to MCCMH and may not identify any individual served in any publicized or distributed report of that research or otherwise disclose the identity of individual(s) served.

4. All procedures for data collection shall describe the method for ensuring that the identity of the individual participants shall be protected.

5. The reporting of research results or any references to research conducted at MCCMH by a Principal Investigator or collected by MCCMH and utilized by a Principal Investigator shall use only aggregate data rather than individual confidential individual served information.

6. Documentation necessary:

   a. When confidential individual served information shall be obtained during the research project, the individual served must sign a MCCMH Informed Consent for Research Projects form, (Exhibit D), or the research project's own form, if the latter conforms to Form Exhibit D. This form should state that confidential information of individuals served will not be publicized.

   b. The individual's served informed consent is **not** necessary when the data supplied to or obtained by a research project contains no identifiable information concerning an individual served (i.e., name, address, readily identifiable information).

III. Procedures for Review of Research Projects / Proposals

A. Prior to the Review Meeting

1. The Principal Investigator shall be sent a package with cover letter, describing the procedures herein and documentation necessary for review of his/her research proposal. The package shall include a copy of MCCMH MCO Policy 2-025, Research Proposal Guidelines, Exhibit A; Research Proposal Cover Sheet, Exhibit B; Format for research Proposals, Exhibit C; Informed Consent for Research Projects (sample), Exhibit D; Acknowledgment of Confidentiality – Principal Investigators, Exhibit E; Publication Agreement, Exhibit F; and Report of Unanticipated Problems, Exhibit G.

2. The Principal Investigator shall prepare a brief abstract of the research proposal and submit it to the C & R Committee Chairperson.

3. The Chairperson shall seek input from an appropriate C & R Committee member, who may, if necessary, consult with the MCCMH Project Coordinator, to determine the functionality or practicality of the project.

4. The Principal Investigator shall complete the Research Cover Sheet and Proposal Forms (Exhibits B through F) and submit them to the Chairperson of the C & R Committee, who shall forward copies to each C & R Committee member and keep one additional copy for the file.

5. The C & R Committee Chairperson, or his/her designee, shall review the application for completeness, using the criteria outlined in Part B, Project Requirements. If it is incomplete, the Chairperson or designee shall return the application to the Principal Investigator for completion and resubmission.

6. The Chairperson shall also establish the date on which the C & R Committee will meet, place the proposal on the agenda, inform the C & R Committee members and the Principal Investigator of the meeting and distribute the proposals to the members. The Chairperson shall attempt to respond to the proposal within five (5) working days of receipt.

B. The Approval Process

1. The Chairperson or designee shall convene the meeting.

2. The Principal Investigator shall attend meetings of the C & R Committee and answer questions relevant to the proposed research.

3. The C & R Committee shall discuss and evaluate the project proposal considering the criteria in Part A.

4. The C & R Committee shall attempt to recommend action to the Chief Executive Officer regarding research proposals within four weeks of receiving the proposal. If the C & R Committee is unable to make a recommendation in that time, notification shall be sent to the Principal Investigator.

5. Decision regarding recommendation of the C & R Committee shall be made by consensus of the Committee members. Dissenting opinions of individual members may be attached to the recommendation for Chief Executive Officer review.

6. The C & R Committee may recommend:

   a. Approval of the research proposal with no modifications;

   b. Approval of the research proposal to be returned to the Principal Investigator with suggested minor or major modifications;

   c. Approval of the research proposal with identified deviation or waiver of select provisions of the policy with sufficient written rationale and justification for each affected provision submitted to the Chief Executive Officer; or

   d. Rejection of the research proposal.

   The Principal Investigator may withdraw the research proposal at any time.

7. The C & R Committee shall send its recommendations, in writing, along with any dissenting opinion, to the Chief Executive Officer, with a copy to the MCCMH Project Coordinator, specifying the suggestions for modification or reasons for rejection, as appropriate.

8. The Chief Executive Officer will review the recommendations of the C & R Committee, and may take the following action:

   a. Request review by MDHHS' Institutional Review Board;

   b. Approve the proposal;

   c. Request the proposal be returned to the author for suggested modification, without rendering a denial; or

d. Reject the proposal, specifying reason(s) for the rejection.

9. The C & R Committee Chairperson, as a representative of the MCCMH Chief Executive Officer, shall communicate the Chief Executive Officer's action in writing to the Principal Investigator and place a copy of all pertinent materials in the C & R Committee file. The recommendation shall include his/her approval, requests for modification for correction of deficiencies or reasons for rejection, as appropriate.

C. After Approval

1. Proposal modifications shall be negotiated with the Principal Investigator by the C & R Committee Chairperson, as a representative of the Chief Executive Officer's office, or designee.

2. The course of the implementation of the proposal shall be monitored at periodic intervals by the MCCMH Project Coordinator as appropriate to the research design, but not less than semi-annually during the life of the project.

3. The Principal Investigator shall furnish the MCCMH Project Coordinator with documentation indicative of:

   a. Monitoring participants for willingness to continue participation;

   b. Monitoring participants to ascertain if unanticipated risks have arisen; and

   c. Adherence to study methodology.

4. The MCCMH Project Coordinator or his/her designee shall review a sampling of the individual(s) sesrved information to be released to ensure that adequate safeguards protecting individual served confidentiality have been observed.

5. If the MCCMH Recipient Rights Director or the MCCMH Project Coordinator determines that the release of information would be harmful to individuals served, she/he shall recommend to the full C & R Committee and the Chief Executive Officer that authorization for the research or use of the information be withdrawn.

6. The Recipient Rights Director shall assist in the monitoring, with particular emphasis on the areas of obtaining informed consent and the process for terminating participation.

7. The MCCMH Project Coordinator shall submit a report to the C & R Committee, which will, after review, submit it to the MCCMH Chief Executive Officer. The report shall include the Principal Investigator's documentation and the MCCMH Project Coordinator's assessment as to whether the implementation of the research project complied with the approval issued by the Chief Executive Officer.

8. The MCCMH Project Coordinator shall monitor all approved studies involving human participants via site visits for the purpose of:

   a. Determining the continued willingness of its participants to participate;

   b. Ascertaining if unanticipated risks have arisen and that such information has been communicated to the participants; and

   c. Determining that studies adhere to their approved methodology.

9. Upon completion of the research, the Principal Investigator, shall:

   a. Attempt to remove any confusion, misinformation, stress, physical discomfort, or other harmful consequences that may have arisen with respect to the participants as a result of the procedures; and

   b. Be responsible for communicating the purpose, nature, outcome and possible practical or theoretical implications of the research to the staff of the program in a clear and comprehensible language and manner.

10. The Principal Investigator shall:

    a. Notify the C & R Committee Chairperson of any non-MCCMH funds requested from the outside, if any, and, if and when funding is granted, the date the funding is to begin, the amount of funding, and the date of the initiation and termination of the project.

    b. Notify the C & R Committee Chairperson of any proposed changes in major objectives, substantive design, risk to participants, schedule for completion or change in personnel; and

    c. Submit an annual project report and a final report, in publishable form, at appropriate times to the C & R Committee, which will, after review submit the reports to the MCCMH Chief Executive Officer.

11. The C & R Committee Chairperson shall evaluate the source of any external funds for potential conflicts of interest with MCCMH mandates and, should a conflict of interest be found, he/she shall notify the Chief Executive Officer as soon as possible.

12. The Research C & R Committee shall approve or disapprove project changes, review the annual and terminal project reports, and take any necessary action.

D. Emergency Procedures

1. The Principal Investigator or MCCMH Project Coordinator of an approved research project shall inform the Research C & R Committee of any problems involving unanticipated risks to participants within 24 hours of detection.

2. Should the C & R Committee have serious concerns about an aspect of the research project, the MCCMH Project Coordinator or the Chairperson of the C & R Committee may suspend the project pending review by the C & R Committee.

3. The C & R Committee shall meet to review and resolve problems involving unanticipated risks to participants prior to the continuation of the research project.

4. Based upon review and analysis of the risk factors, the C & R Committee shall recommend to the MCCMH Chief Executive Officer the resumption, revision, or termination of the research project.

5. The Chief Executive Officer shall exercise the final authority in approval or disapproval of the continuation of a research project.

E. Publication

1. The Principal Investigator shall submit to the C & R Committee all manuscripts, written or electronic documents relating to MCCMH directly operated or contracted network providers or individuals served undertaken by MCCMH employees, contractual staff, interns, students, volunteers, consultants to contractual agencies, representatives of MDHHS, or other individuals which he/she wishes to publish or distribute outside of MCCMH.

2. The C & R Committee shall review a manuscript or written document under consideration for publication or distribution and forward its written recommendations to the MCCMH Chief Executive Officer.

3. The Chief Executive Officer shall review the C & R Committee's recommendations and forward his/her written approval of the manuscript or document prior to its publication. The Principal Investigator shall not publish a manuscript or written document in the absence of the Chief Executive Officer's written approval.

1. If revisions are made to publications, articles, or reports subsequent to the C & R Committee's review and the Chief Executive Officer's written approval, a revised manuscript must be forwarded to the C & R Committee for its review and also for the Chief Executive Officer's written approval. This includes revisions requested by journal reviewers.

2. The Principal Investigator shall submit an outline of a proposed oral presentation to the C & R Committee for its review, prior to the Chief Executive Officer's written approval, and such outline shall be maintained in the C & R Committee's file located in the administrative offices of MCCMH.

3. The C & R Committee shall maintain a written record of all research proposals and publication submissions, the C & R Committee's review of those requests and its recommendations, the Chief Executive Officer's written approval, and the final reports or publications.

F. Checklist

1. The C & R Committee members may utilize Exhibit H, Research and Educational Training committee Proposal Checklist, as a tool to assist in carrying out their research review function under this policy.

IV. Appendices

Appendix A. Research Proposal Guidelines

Appendix B. Research Proposal Cover Sheet

Appendix C. Format for Research Proposals

Appendix D. Informed Consent for Research Projects (Sample)

Appendix E. Acknowledgment of Confidentiality – Principal Investigators

Appendix F. Proposal Form for Research / Publication / Presentation

Appendix G. Report of Unanticipated Problems

Appendix H. MCCMH Research and Educational Training Committee Research Proposal Checklist

MACOMB COUNTY COMMUNITY MENTAL HEALTH
22550 Hall Road
Clinton Township, MI 48036
(586) 469-5275

RESEARCH PROPOSAL GUIDELINES

I. GENERAL PRINCIPLES

All research relating to the Macomb County Community Mental Health (MCCMH) Board operations, (directly operated or contractual), and/or individuals served undertaken by board employees, contractual staff, interns, students, volunteers, staff or consultants to contractual agencies, representatives of the Michigan Department of Health and Human Services, or other individuals must be reviewed by the MCCMH Clinical Practice and Research Committee and receive the prior written approval of the Chief Executive Officer.

II. FORMAL APPLICATION

The Principal Investigator must submit a proposal which shall include the following materials:

The proposal should begin with the Cover Sheet (A), followed by the Research Proposal form (B), the Informed Consent for Research Projects form (C), the Acknowledgment of Confidentiality – Principal Investigators (D), the Publication Agreement (E), the Report of Unanticipated Problems (F) and any Appended Information (G). The Report of Unanticipated Problems (F) is for the benefit of and should remain with the research project.

A. Cover Sheet

Each proposal shall be accompanied by a cover sheet which provides the following information:

1. The title of the project;
2. The name, position and institutional affiliation of the Principal Investigator;
3. The performance site(s) – if different from the above institutional affiliation;
4. The proposed start-up date and anticipated completion date;
5. Abstract of the proposed project (not to exceed 250 words); and
6. Ten key words which may be used to code and identify the research project.

The Cover Sheet may be used or may be seen as a model to be followed.

B. Research Proposal Form

The Research Proposal shall contain the following:

1. Title of the project

2. Statement of the problem(s)

   This should include a review (with bibliography) of previous research as well as the hypothesis(es), specific objectives, references, questions which the current research will attempt to answer, and a history of prior approvals.

3. Method

   a. Subjects

   b. Instrumentation / Resources

   c. Procedures

   d. Budget (funding source, reimbursements, procedures for payment)

   e. Anticipated time frame or duration for project completion

C. Informed Consent for Research Projects

D. Acknowledgment of Confidentiality – Principal Investigators

E. Publication Agreement

F. Report of Unanticipated Problems – to remain with research project.

G. Appended Information

1. Subject Protection

   a. An assessment of any potential risks – physical, psychological, or social; the likelihood and seriousness of such risks; the reasons why these risks are necessary;

   b. An assessment of any possible benefits and/or the importance of knowledge to be gained;

   c. Procedures for obtaining informed consent should be described in detail – a copy of the consent form; and

   d. Procedures for protecting the health, safety, and welfare of subjects, including confidentiality.

2. Vitae for the Principal Investigator and research associates, including publications, should be included;

3. Information gathering instruments – if possible, it would be helpful for review if copies of all instruments (questionnaires, tests, etc.) were included.

III. FORMAT FOR RESEARCH PROPOSALS

INTRODUCTION AND PURPOSE:	State why the project should be done; include in this statement prior research or other efforts which would suggest that this project is needed; the participant population; and the intended audience.
HYPOTHESIS:	State your hypothesis(es) and/or expected results.
METHODOLOGY:	The methodology section must address the following issues: a) The targeted participants of the study – if individuals served of MCCMH services are to be intended participants in the study you must address how informed consent shall be obtained, how the participants' rights to privacy and confidentiality will be protected and identify any potential risks to the participants. If risks are identified, you must address how those risks can be minimized as well as address the potential benefits that offset those risks; b) The anticipated number of participants for the study; c) The research design to be employed; d) Copies of any instruments which shall be used to either survey, interview, or collect date for the project; e) The anticipated analysis; f) Any support necessary for the project involving MCCMH resources (e.g., staff, clerical, phone, etc.)
IMPACT:	Describe the potential impact of this project for the MCCMH Board, MCCMH individuals served, mental health research, and/or the community as a whole.
PROFESSIONAL CREDENTIALS:	Please indicate who will be the Principal Investigator responsible for interacting with the C & R Committee during the course of this project. Provide information regarding this person's professional credentials and his/her vitae. If appropriate, indicate the level of training which data collection staff has <u>had</u> relating to the collection of mental health data.
PROPOSAL FUNDING:	Please indicate whether the Project is being funded, by whom, and in what amounts.
ATTACHMENTS:	

IV. FINAL CONSIDERATIONS

A. Approval of your research project must be conducted in accordance with MCCMH MCO Policy 2-025 (enclosed) and be consistent with acceptable professional and scientific standards.

B. The completed application should be forwarded to the Chairperson of the Clinical Practice and Research Committee.

C. Any questions regarding this policy should be directed to the Chairperson of the Clinical Practice and Research Committee.

MACOMB COUNTY COMMUNITY MENTAL HEALTH

22550 Hall Road Clinton
Township, MI 48036 (586)
469-5275

RESEARCH PROPOSAL COVER SHEET

TITLE OF PROJECT:

Principal Investigator

NAME:

POSITION:

INSTITUTION:

PERFORMANCE SITE(S) -- IF DIFFERENT FROM ABOVE:

PROPOSED START-UP DATE:

ESTIMATED COMPLETION DATE:

ABSTRACT (NOT TO EXCEED 250 WORDS):

KEY WORDS (NOT TO EXCEED 10) TO CATEGORIZE PROJECTS:

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RESEARCH, PUBLICATION AND RELATED PROJECTS

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Research requests must submit a proposal which follows the format provided below. The proposal should have the attached cover sheet completed and the sheet and the proposal should be forwarded to the Chairperson of the C & R Committee.

Approved research projects must be conducted in accordance with MCCMH Policy 2-025, federal and state laws, and be consistent with acceptable professional and scientific standards.

Any questions regarding this policy should be directed to the Chairperson of the C & R Committee.

FORMAT FOR RESEARCH PROPOSALS

INTRODUCTION AND PURPOSE:	State why the project should be done; include in this statement prior research or other efforts which would suggest that this project is needed; the participant population; and the intended audience.
HYPOTHESIS:	State your hypothesis and/or expected results.
METHODOLOGY:	The methodology section must address the following issues: a) the targeted participants of the study -- if individuals served of MCCMH services are to be the intended participants in the study you must address how informed consent shall be obtained, how the participants' rights to privacy and confidentiality will be protected, and identify any potential risks to the participants. If there are risks identified you must address how those risks can be minimized as well as address the potential benefits to offset those risks; b) the anticipated number of participants for the study; c) the research design to be employed; d) copies of any instruments which shall be used to either survey, interview, or collect data for the project; e) the anticipated analysis; f) any support necessary for the project involving MCCMH resources (e.g., staff, clerical, phone, etc.)
IMPACT:	Describe the potential impact of this project for the MCCMH Board, MCCMH individuals served, mental health research, and/or the community as a whole.
PROFESSIONAL CREDENTIALS:	Please indicate who will be the Principal Investigator responsible for interacting with the C & R Committee during the course of this project. Provide information regarding this person's professional credentials and his/her vitae. If appropriate, indicate the level of training which data collection staff has had relating to the collection of mental health data.
PROPOSAL FUNDING:	Please indicate whether the Project is being funded, by whom, and in what amounts.

Attachments:

MACOMB COUNTY COMMUNITY MENTAL HEALTH

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469-5275

Informed Consent for Research Projects

Agency: _____ Case Number: _____

The undersigned hereby grants consent for _____, an individual served/guardian/staff member/intern/volunteer of Macomb County Community Mental Health (MCCMH), to participate in the following research project:

This consent encompasses only the following types of techniques: _____

_____

_____

_____

_____

As an individual served/ guardian,

- I have been provided with a verbal and written explanation of the program procedures, a description of the potential risks and discomforts that might be experienced, and a description of the potential benefits of the program.
- I have had an opportunity to ask questions and have been provided with answers to inquiries concerning the program and alternative programs, if any.
- I understand the rationale for the procedures, risks, consequences, and other relevant factors.
- If I have any additional questions, I understand that _____ is the

  Research and Educational Training Committee member resource person for the research project and that I should direct questions concerning the research to him/her.
- I realize that I may withdraw consent and discontinue participation in the research project at any time without prejudice.
- I also realize that during my participation in the research project, I can turn to the Principal Investigator, _____, who will attempt to alleviate any confusion, misinformation, stress, physical discomfort, or other harmful consequences I might experience.

At this time, I give consent for my participation / for _____'s participation in the research project. I am aware that information obtained from me may be used in this project. However, I understand in reporting or publicizing the results, my individual identifiable confidential information will <u>not</u> be included.

The research project has been explained to my satisfaction by:

_____ on _____
(MCCMH staff or contract agent) (Date)

This consent expires on ____ / ____ / ___, within one year, or on the termination of services, or whenever interim circumstances or changes in the research project substantially affect the risks or other consequences or benefits reasonably to be expected.

_____ _____
WITNESS' SIGNATURE date INDIVIDUAL'S SERVED SIGNATURE date

_____ _____
WITNESS' SIGNATURE date GUARDIAN'SIGNATURE date
(If applicable) (If applicable)

_____
WITNESS' SIGNATURE date
(If applicable)

NOTES: _____

_____

_____

_____

_____

_____

MACOMB COUNTY COMMUNITY MENTAL HEALTH

RESEARCH PROJECT

ACKNOWLEDGMENT OF CONFIDENTIALITY – Principal Investigators

In the process of gathering, preparing, and presenting date or any other individual served information for my research project involving Macomb County Community Health Board individuals served, I understand that I am obligated to maintain the confidentiality of individually identifiable information at all times in keeping with the provisions of the Michigan mental Health and Public Health Codes, the Code of Federal Regulations governing substance abuse, or any other Federal or State laws. I further understand that any violation of the confidentiality of this information may result in termination of the agreement to do research with MCCMH individuals served, and initiation of legal proceedings against you that may include the imposition of civil and/or criminal penalties

_____ _____

Signature Date

_____ _____

Witness Date

MACOMB COUNTY COMMUNITY MENTAL HEALTH

PROPOSAL FORM FOR RESEARCH / PUBLICATION / PRESENTATION

REQUEST

Applicant: Please complete the REQUEST section of the proposal, sign the ACKNOWLEDGMENT OF CONFIDENTIALITY, and forward the full proposal packet to the Macomb County Community Mental Health Chief Executive Officer and Chairperson of the Clinical Practice and Research (C & R) Committee.

Please ✓: ☐ RESEARCH ☐ PUBLICATION ☐ PRESENTATION

Submitted to: _____

Requested by: _____

Date of Request: _____

Address: _____ Phone: _____

Name of Immediate Supervisor: _____

Supervisor's Phone: _____

Project Title: _____

(Attach a description using the approved format)

RECOMMENDATION

Chairperson of the C & R Committee: _____

Title: _____

Recommendation:
- ☐ Denied
- ☐ Approved as requested
- ☐ Approved, with the following conditions / exclusions

Comments: _____

_____

_____

_____

Chairperson's Signature: _____ Date: _____

Chairperson's Signature: _____ Date:

Address: _____ Phone: _____

MACOMB COUNTY COMMUNITY MENTAL HEALTH

22550 Hall Road
Clinton Township, MI 48036
Phone: (586) 469-5275

PROPOSAL FORM FOR RESEARCH / PUBLICATION / PRESENTATION

Chief Executive Officer: _____

Final Disposition:
- ☐ Denied
- ☐ Approved as requested
- ☐ Approved, with the following conditions

Comments: _____

_____

_____

_____

Chief Executive Officer's Signature: _____ Date: _____

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Phone: (586) 469-5275

RESEARCH, PUBLICATIONS AND RELATED PROJECTS

All manuscripts or written documents and/or oral presentations relating to MCCMH operations (directly or contractually) and/or individuals served undertaken by Board employees, contractual staff, interns, students, volunteers, consultants to contractual agencies, representatives of the Michigan Department of Health and Human Services) or other individuals which have been prepared for the purpose of publication or distribution outside of the MCCMH Mental Health Board must be reviewed by the MCCMH Clinical practice and Research (C & R) Committee and approved by the MCCMH Chief Executive Officer prior to their dissemination.

The manuscript should have the Request for Publication cover sheet attached to it and forwarded to the Chairperson of the C & R Committee.

FORMAT FOR PUBLICATIONS, ARTICLES AND/OR REPORTS

You may submit articles or reports in the format required by the target group (e.g., APA Journal, MDHHS, etc.). Those research proposals which were approved by the C & R Committee should include an acknowledgment of the MCCMH Mental Health Board's cooperation and participation in the project.

MACOMB COUNTY COMMUNITY MENTAL HEALTH
RESEARCH AND EDUCATIONAL TRAINING COMMITTEE

REQUEST FOR PUBLICATION

COVERSHEET

TITLE OF PROJECT:

Principal Investigator

NAME: _____

POSITION: _____

INSTITUTION: _____

PERFORMANCE SITE(S) -- IF DIFFERENT FROM ABOVE:

PROPOSED START-UP DATE: _____

ESTIMATED COMPLETION DATE: _____

ABSTRACT (NOT TO EXCEED 250 WORDS):

KEY WORDS (NOT TO EXCEED 10) TO CATEGORIZE PROJECTS:

MACOMB COUNTY COMMUNITY MENTAL HEALTH

22550 Hall Road Clinton
Township, MI 48036 (586)
469-5275

REPORT OF UNANTICIPATED PROBLEMS

Title of Research Project:
Principal Investigator:
Name:
Position:
Institution:
Performance Site(s) (if different from above):
Supervisor of the Unit:
Date Research Project Began:
Estimated Completion Date:
Date of discovery of unanticipated problem(s):
UNANTICIPATED PROBLEM(S) (not to exceed 250 words)

MACOMB COUNTY COMMUNITY MENTAL HEALTH
22550 Hall Road
Clinton Township, MI 48036
(586) 469-5275

MCCMH RESEARCH AND EDUCATIONAL TRAINING COMMITTEE RESEARCH PROPOSAL CHECKLIST

Component	Approve	Disapprove	Recommendations
1. Health, safety, and general welfare of the individual(s) served involved as subjects of the research; appropriateness and adequacy of the methods used to obtain informed consent.			
2. Potential risks for individual(s) served who are subjects of the research.			
3. Benefits of the project, both to the individual(s) served/ long-termed benefits that would accrue in the field of mental health.			
4. Ethical issues.			
5. Scientific merit.			
6. Validity of t he proposal in terms of the importance of the research problem.			
7. Scientific soundness in terms of adequacy of the experimental design.			
8. The methodology of the study.			
9. The specific research design and methods to be used,			
10. The research project's administrative and territorial boundaries.			
11. The proposed timeline (starting and termination dates).			
12. Roles that the agency, staff and individuals served or participants are to perform in the research			
RESEARCH PROPOSAL CHECKLIST Page 1			

Component	Approve	Disapprove	Recommendations
13. Projected consequences of the research project including: a. Short and/or long-term results and/or discomforts to participants, b. Implications of the research project and its findings on community mental health operations.			
14. Proposed research can be expected to have benefits that outweigh the risks to participants including risks based on the competence of the investigators and availability of resources.			
15. All individuals who serve as human subjects be adequately informed both orally and in writing in their spoken language regarding the nature of the research project. This information should include but not be limited to: a. Procedures to be used including any which are experimental. b. Possible attendant short and/or long-term risks and discomforts. c. Anticipated benefits the participants should anticipate to self and others. d. Any alternative methods. e. The expected duration of the study. f. The freedom to ask questions and to withdraw consent at any time.			
16. All individuals served participating as human subjects have given prior signed informed consent.			
17. Individuals who serve as human subjects, and/or legally responsible representative(s), be adequately informed prior to giving their signed consent. Such information shall have prior approval of the C & R Committee and shall include: a. A written summary of the oral instructions given to the participants. b. The content of the informed consent forms to be presented to the participants.			
18. Whenever signed informed consent is given it is done so with signed concurrence by a qualified professional attesting to the consenter's comprehension of information and autonomy of consent.			

RESEARCH PROPOSAL CHECKLIST Page 2

	Approve	Disapprove	Recommendations

Component			
19. Identify a committee member as a Project Coordinator for a particular research project. S/he shall be available for subjects who wish to ask questions and discuss reservations concerning the study.			
20. Professional credentials, qualifications, and vitae of the Principal Investigator and his/her Assistants. Reviewed by: Date of Review:			
Committee Chairperson			
RESEARCH PROPOSAL CHECKLIST Page 3			