SHIAWASSEE COUNTY COMMUNITY MENTAL HEALTH AUTHORITY

POLICY AND PROCEDURE MANUAL

Section: Recipient Rights	Effective Date: 9/17/91
Policy Number: 26	Last Revision Date: 4/2/09
Subject: **Research Review Committee**	Page: 1 of 8

Policy

It is the policy of Shiawassee County Community Mental Health Authority (SCCMHA) that all proposed research projects using SCCMHA consumers as subjects will be reviewed by and approved or disapproved by the Research Review Committee.

Purpose

To ensure that all proposed research projects which make use of human subjects are subjected to rigorous review by a committee composed of qualified individuals.

To ensure compliance with all applicable state and federal laws, regulations and standards and the requirements of third party reimbursers and accrediting bodies regarding the use of human subjects in research.

Application

This policy applies to all research projects proposed by SCCMHA employees, contractual providers, outside entities including students and volunteers using SCCMHA consumers as subjects.

Definitions

Research: A systematic investigation designed to develop or contribute to generalizable knowledge.

Human subject: A living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.

Intervention: Includes both physical procedures by which data is gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction: Includes communication or interpersonal contact between investigator and subject.

Private information: Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (i.e. a medical record). Private information must be individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Minimal risk: The risk of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Standards

1. An interdisciplinary Research Review Committee having at least five members appointed by the Chief Executive Officer (CEO) will be convened on an as-needed basis to review all proposed research projects using SCCMHA consumers as subjects.

    a. Members will be qualified by training and experience in the research area being reviewed, as well as represent a diversity of ethnic and cultural backgrounds and a sensitivity to such issues as community attitudes.

    b. Since the committee must ascertain the acceptability of the proposed research in terms of the agency's commitments and regulations, applicable law, and standards of professional conduct and practice membership will include a person or persons knowledgeable in these areas.

    c. At least one member will have primary concerns in nonscientific areas (i.e. lawyers, ethicists, members of the clergy).

    d. At least one member will not be formally affiliated with the agency nor have an immediate family member who is affiliated with the agency.

    e. Members will not be directly associated with the research project under consideration.

    f. Members will not be all of one sex nor of one profession.

    g. The committee may at its discretion invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the committee. These individuals may not vote with the committee.

2. All consumers asked to participate in a research project will be given information (as described in VI.B.8.) before being asked to give their consent.

3. All research project participants will sign a consent form that indicates their willingness to participate in the project.

4. Refusal to participate in a research project is not cause for denying or altering the provision of indicated services to a consumer.

5. Participants are allowed to withdraw consent and discontinue participation in a research project at any time without affecting their status in treatment.

6. Participants' basic human dignity, privacy and confidentiality will be protected at all times except if contrary to law.

7. Upon completion of the research procedures the principal investigator will 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.

8. Investigators and others directly involved in the research, both in obtaining consent and in conducting the research, will adhere to professional standards concerning the conduct of research and are guided by the regulations of the U.S. Department of Health and Human Services and applicable law and regulation concerning the protection of human rights.

9. Upon completion of the research and at other times deemed appropriate by the Research Review Committee, the principal investigator will submit a written report to the Research Review Committee and the CEO.

10. Written records of all Research Review Committee meetings and activities will be retained for a minimum of three years after the completion of a research project.

Procedure

1. The principal investigator will submit a written request briefly describing the proposed research project to the CEO. If the CEO determines that the project may be one in which the agency has reason to enter into participation, he/she will convene a Research Review Committee to review thoroughly the proposed project. The CEO will appoint one member of the committee to serve as the chairperson. The principal investigator will be notified of the action taken by the CEO.

2. The principal investigator will submit the following written information to the committee for its review:

a. Description of the research project.

b. Qualifications of the principal investigator and any other individuals conducting the research.

c. The benefits of the research in general.

d. The benefits and risks to the subjects.

e. The benefits to the agency and the Board.

f. The possible disruptive effects of the project on the agency's operations.

g. The compliance of the research design with accepted ethical standards.

h. The process to be used to obtain informed consent from the participants. The proposed consent form will be submitted for committee review.

   No informed consent, whether oral or written, may include any language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights or releases or appears to release the investigator, the sponsor, the agency or its agents from liability for negligence.

   The consent form must include the following information presented in a way that is clearly and easily understood by the prospective subjects and/or the prospective subject's parent or legal guardian if the prospective subject is a minor or a person who is legally or functionally incompetent to provide informed consent:

   i. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

   ii. A description of any reasonably foreseeable risks or discomforts to the participant.

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

   iv. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

   v. A statement regarding the subject's right to privacy and confidentiality.

vi. A statement that participation is voluntary and that the subject may discontinue participation at any time without affecting his/her status in treatment.

vii. A place for the name of the person who supplied the subject with the information and a place for the subject and/or parent or legal guardian to sign and date the form indicating his/her informed consent to participate in the project.

viii. The subject will be given a copy of the signed consent form.

3. The Research Review Committee will meet at a time and place designated by the chairperson of the committee. A majority of members present including one whose primary concerns are in a nonscientific area will constitute a quorum.

4. The Research Review Committee will review and have authority to approve, require modifications in (to secure approval), or disapprove all proposed research projects.

5. The Research Review Committee will use the following criteria to review the proposed research project. All of the following requirements must be satisfied in order to approve the project:

   a. Risks to subject are minimized:

      i. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.

      ii. Whenever appropriate by using procedures already being performed on subjects for diagnostic or treatment purposes.

   b. Risks to subjects are reasonable in relation to anticipated benefits if any to subjects and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits the Research Review Committee should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The Research Review Committee should not consider possible long-range effects of applying knowledge gained in the research (i.e. the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

   c. Selection of subjects is equitable. In making this assessment the Research Review Committee should take into account the purposes of the research and the setting in which the research will be conducted.

d. Informed consent will be sought from each prospective subject and/or parent or legal guardian.

e. Informed consent will be appropriately documented.

f. Where appropriate the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.

g. Where appropriate there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

h. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or sever physical or mental illness or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

6. In order for the proposed research project to be approved it must receive the approval of a majority of those members present at the meeting.

7. The chairperson of the Research Review Committee will notify in writing the CEO and the principal investigator of the committee's decision to approve or disapprove the proposed research project or of modifications required to secure Research Review Committee approval. If the Research Review Committee disapproves the project it will include in its written notification a statement of the reasons for its decision and provide the investigator an opportunity to respond in person or in writing.

8. Final approval or disapproval of a research project rests with the CEO. However, he/she may not approve a project if it has not been approved by the Research Review Committee.

9. The Research Review Committee will conduct continuing review of approved research appropriate to the degree of risk, but not less than once per year, and will have the authority to observe or have a third party observe the consent process and the research.

10. The Research Review Committee will have the authority to suspend or terminate approval of research that is not being conducted in accordance with its requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval will include a written statement of the reasons for the committee's action and will be reported promptly to the investigator and the CEO.

11. The following written records will be kept by the Research Review Committee for at least three years after completion of the research:

    a. Copies of all research proposals reviewed, approved sample consent documents and progress reports submitted by investigators.

    b. Minutes of Research Review Committee meetings which will be in sufficient detail to show attendance at the meetings, actions taken, the vote on these actions including the number of members voting for, against and abstaining, the basis for requiring changes in or disapproving research and a written summary of the discussion of disputed issues and their resolution.

    c. Records of continuing review activities.

    d. Copies of all correspondence.

    e. A list of Research Review Committee members.

    f. Written procedures for receiving notification of and acting upon changes in an approved research design and for insuring prompt reporting to the Research Review Committee of unanticipated problems involving risks to subjects or others.

References

Consolidated Standards Manual, 1991, Joint Commission on Accreditation of Healthcare Organizations.

Code of Federal Regulations; Title 45; Part 46 - Protection of Human Subjects; Revised as of March 8, 1983

Approved by: Signed by Jerry Walden 04/02/09
Board Chairperson Date

Signed by Scott Gilman 04/02/09
Chief Executive Officer Date

Review/Revision Dates:

Date:	By:
1992-2008	Review by Board
4/2/09	New formatting
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