LAPEER COUNTY COMMUNITY MENTAL HEALTH

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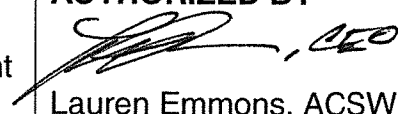
CHAPTER Recipient Rights	**CHAPTER** 04	**SECTION** 003	**SUBJECT** 60
SECTION Individual Rights	**DESCRIPTION** Research Guidelines and Ethical Standards		
WRITTEN BY Maureen Parsons, BSW, QI Assistant	**REVISED BY** Lisa Ruddy, BS, CHESQuality Improvement Coordinator	**AUTHORIZED BY**  Lauren Emmons, ACSW CEO	

APPLICATION:

☒CMH Staff	☒Board Members	☒Provider Network	☒Employment Services Providers
☐Employment Services Provider Agencies	☒Independent Contractors	☒Students	☒Interns
☒Volunteers	☐Persons Served		

POLICY:

Lapeer County Community Mental Health (LCCMH) programs may conduct research or participate in research conducted by a university, hospital, or other institution with adults. LCCMH will not support or authorize research with children.

STANDARDS:

A. Respect for persons served will be maintained at all times. Respect for persons served involves two distinct moral requirements:

   1. Acknowledging autonomy

   2. Protecting those with diminished capacity

B. Persons served participating in research will be treated in an ethical manner by making efforts to secure their well-being. Research conducted will:

   1. Do no harm

2. Maximize possible benefits to the person served

C. Benefits and risks of research will be distributed among participants fairly and equally.

D. Persons served participating in research have the right to discontinue participation at any point in the research and for any reason they see fit.

E. All documentation and information regarding research approval, process, and final reporting will be stored with the Chief Executive Officer (CEO).

F. Corporate Compliance Program Standards shall be enforced and followed in all research. See LCCMH Policy 01.002.10 Corporate Compliance Program.

PROCEDURES:

A. All internal and external research projects proposed to be conducted in LCCMH facilities will be reviewed and a determination of approval or denial will be made by the CEO in consultation with the Recipient Rights Officer or the Behavior Treatment Plan Review Committee.

B. Any external institution seeking research approval within LCCMH will produce documentation of approval or exemption of research with human subjects determined by an Institutional Review Board (IRB). Any research with IRB approval for researching human subjects will code data as unidentifiable prior to publication of research findings. IRB exempt research will only include data coded aggregate form to eliminate individual identifying information.

C. All internal research data and Protected Health Information (PHI) will be reported in coded aggregate form to eliminate individual identifying information.

D. All participants must give informed consent to participate in the research.

E. The informed consent process shall include elements:

1. Information (purpose, risks, benefits, duration, how to access research outcome reports, rights to information obtained)

2. Comprehension

3. Voluntariness (including the right to discontinue)

F. Informed consent forms will be provided by the researcher or the institution conducting research.

G. Informed consent will be documented and forms will be signed prior to the release of any PHI. See LCCMH Policy 02.003.45 Informed Consent.

H. All researchers or institutions approved to conduct research at LCCMH will adhere to LCCMH and HIPAA confidentiality standards.

I. Researchers or institutions must sign a LCCMH confidentiality agreement prior to any contact with participants or access to PHI.

J. Researcher's practices will include encryption, document shredding, locking doors and file storage areas, and use of passwords and codes for access to data containing any PHI.

K. All possible risks to persons served will be investigated thoroughly in consideration of implementing internal and external research projects with persons served at LCCMH. The nature and scope of risks and benefits will be assessed in a systematic manner.

L. A fair and equal process, procedure, and outcomes in selection of research participants.

DEFINITIONS:

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective. Activities which meet this definition constitute research for purposes of this policy.

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

Protected Health Information (PHI): Any information that can be used to identify a person, whether living or deceased, that relates to the person's past, present, or future

physical or mental health condition, including healthcare services provided and payment for those services.

Informed Consent: Written informed consent on the part of a person served, empowered guardian or parent (if a minor). All of the following are elements of informed consent:

a. Legal Competency: An individual will be presumed to be legally competent. This presumption may be rebutted only by a court appointment of a guardian, or exercise by court of guardianship powers, and only to the extent of the scope and duration of the guardianship. An individual will be presumed legally competent regarding matters that are not within the scope and authority of the guardianship.

b. Comprehension: An individual must be able to rationally understand what the personal implication of providing consent will be based upon the information provided.

Institution: Any public or private entity or agency including federal, state, and other agencies.

Internal: Research conducted by persons employed by LCCMH or Contracted Agency or Personnel.

External: Research conducted by persons or institutions not affiliated with Lapeer CMH.

Institutional Review Board (IRB): Sometimes called an independent ethics committee, ethical review board, or research ethics board. An IRB is a committee that is formally designated to approve, monitor, and review biomedical and behavioral research involving human subjects. IRBs are most often part of a college or university.

REFERENCES:

LCCMH Policy #02.003.45 Informed Consent

U.S. Department of Health & Human Services, Guidance on Engagement of Institutions in Human Subjects Research, 2008
45 CFR 46

National Research Act, 1974
Public Law 93-348, Title II

The Belmont Report, 1979
Ethical Principles and Guidelines for Protection of Human Subjects of Research

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