

POLICIES AND PROCEDURE MANUAL

Chapter:	Quality		
Title:	Research		
Policy: <input type="checkbox"/> Procedure: <input type="checkbox"/> Page: 1 of 2	Review Cycle: Annually Author: Chief Compliance Officer, Quality Improvement Council	Adopted Date: 09.02.2014 Review Date: 07.09.2019 Revision Eff. Date: 11.2015	Related Policies: Quality Management

Purpose:

To protect the rights and well-being of human subjects of research conducted by Mid-State Health Network (MSHN) and/or its provider network and to ensure compliance with the Protection of Human Subjects Act, 45 CFR, Part 46 and the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

Policy:

Prior to initiation of research by MSHN and/or its provider network MSHN will submit Institutional Review Board (IRB) application material for all research involving human subjects that is conducted in programs sponsored by the Michigan Department of Health and Human Services (MDHHS) or in programs that receive funding from or through the State of Michigan. The application and approval material will be submitted to the MDHHS's IRB for review and approval or for acceptance of the review by another IRB. All such research must be approved by a federally assured IRB, but the MDHHS's IRB can only accept the review and approval of another institution's IRB under a formally approved interdepartmental agreement. The manner of the review will be agreed upon between the MDHHS's IRB Chairperson and the Contractor's IRB Chairperson or Executive Officer(s).

Research initiated prior to MSHN contracting shall be acceptable provided, upon request, the responsible CMHSP can provide evidence of appropriate MDHHS IRB or alternative review.

All research and related projects shall be conducted in such a manner as to ensure the rights, benefits, and privileges guaranteed bylaw.

All research involving MSHN consumers must be reviewed and approved by a MSHN or MSHN Contractor Research Review Committee before involvement of MSHN subjects in the project. Externally funded projects involving the use of MSHN consumers are to be approved by a MSHN Research Review Board. MSHN acknowledges that grant application time frames may require submission prior to MSHN review; however, approval by the MSHN Research Review Board is required prior to acceptance and implementation of the grant award.

The Research Review Board shall include minimally:

1. A Senior officer of MSHN or its contractors
2. A senior clinician with expertise with the identified population
3. A recipient rights officer
4. A medical director for medically related research

The Research Review Board is responsible for reviewing proposed research projects involving human subjects before submission to the MDHHS's IRB for approval of the research project to ensure that:

1. The rights and welfare of the subjects are protected;
2. Written informed consent is obtained from each subject using appropriate methods;
3. The risks and potential benefits are disclosed to participating subjects; and
4. Review completed (IRB) application material

MSHN may request additional expertise when necessary for adequate review by the Research Review Board. The research review board shall maintain a written record of all research proposals and publication submissions and report at least annually to the MSHN Operations Council.

Applies to

- All Mid-State Health Network Staff Selected MSHN Staff, as follows:
- MSHN’s Affiliates: Policy Only Policy and Procedure Other: Sub-contract Providers
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Definitions

HIPAA: Health Insurance Portability & Accountability Act.

Human subject (as defined by 45 CFR, Part 46.102) means a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information.

IRB: Institutional Review Board reviews, approves, and monitors research that directly or indirectly involves living persons, their issues or personal information, in order to protect the rights of the participants.

MSHN: Mid-State Health Network

MDHHS: Michigan Department of Health & Human Service

Provider Network: Refers to a Community Mental Health Services Program (CMHSP) Participant and a Substance Abuse Provider that is directly under contract with the MSHN PIHP to provide services and/or supports through direct operations or through the CMHSP’s and CA’s subcontractors.

Research Review Board: A body of appointed MSHN or MSHN contractor staff with the knowledge and experience required to function as an IRB.

Research: (as defined by 45 CFR, Part 46.102) means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Other Related Materials

N/A

References/Legal Authority

45 CFR 46: Human Subjects Research
Medicaid Managed Specialty Supports and Services Concurrent 1915(b)/(c) Waiver Program contract, General Provisions, Section 31.0

Change Log:

<u>Date of Change</u>	<u>Description of Change</u>	<u>Responsible Party</u>
09.2014	New Policy	Chief Compliance Officer
08.2015	Update to MDHHS and to include accommodation to research prior to	Deputy Director, Chief Executive Officer
08.2016	Annual Review	Director of Compliance, Customer Service and Quality Improvement
03.2017	Annual Review	Director of Compliance, Customer Service and Quality
03.2018	Annual Review	Director of Compliance, Customer Service and Quality
03.2019	Annual Review	Quality Manager