Title **Northern Lakes CMHA Policies**
Part 106 **Supports and Services – NLCMHA Provided and Contract**
Subpart J **Mental Health Code Protected Recipient Rights**
Policy No. **106.1037**
Subject **Research on Human Subjects (RR)**

Applicability

Policy applies to all Northern Lakes CMHA activities, operations and sites and to all employees except members of the governing body. Policy also applies to any Network Provider and its employees, volunteers, or agents that have elected to adopt and adhere to Northern Lakes CMHA policies and procedures pertaining to Recipient Rights under the terms of its Participating Provider Agreement.

Policy

Any research involving recipients of Northern Lakes CMHA shall be conducted in compliance with all of the following:

1. Federal standards for the protection of human subjects in research administered or funded by the United States Department of Health and Human Services [45 CFR 46 and 21; 21 CFR 50 and 60]; and
2. The Michigan Mental Health Code [PA 258 of 1974, MCL 330.1919(1) and MCL 330.1748(7)(c)]; and
3. Michigan Department of Health and Human Services Administrative Rule 330.1015; and
4. Any other applicable provision of Federal or State law, rule, or regulation; and
5. All applicable Northern Lakes CMHA policies and procedures.

For the purposes of this policy, "research" means systematic investigation, research development, testing, or evaluation designed to develop or contribute to generalized knowledge where a recipient or his or her confidential information is the subject. Activities that meet this definition constitute research, whether or not they are conducted or supported under a program that is considered research for other purposes.

STANDARDS

1. All proposals for research on recipients as human subjects shall first be submitted in writing to the Northern Lakes CMHA Chief Executive Officer, who shall bring the proposal to the Northern Lakes CMHA Executive Team for consideration of its submission to the Michigan Department of Health and Human Services' (MDHHS) Institutional Review Board (IRB).

2. The Executive Team shall provide oversight of the following:
   a. That the purpose of a proposed research project is consistent with the mission and philosophy of Northern Lakes CMHA; and
   b. That the proposed research project will not create an undue burden on Northern Lakes CMHA resources; and
   c. If approved, that the civil and treatment rights of recipients serving as subjects are being protected during the research; and
   d. To intervene on behalf of subjects should the need arise and terminate the research.

4. Any research conducted on a Northern Lakes CMHA recipient shall be subject to all applicable recipient rights protections to which any recipient is entitled, especially including the following:
   a. Recipients who participate as research subjects shall be advised of their rights in an understandable manner prior to initiation of any research project.
   b. Written informed consent shall always be obtained from recipients who may be subjects of research, or from their legally empowered representatives. A full disclosure will be made of all potential risks to the participant in a manner that promotes the opportunity for informed choice, including the right to refuse participation in research activities at any time without penalty.
   c. The dignity, privacy, safety, and confidentiality of recipients participating in research will be protected at all times prior to, during, and after completion of the study under applicable provisions of law. Any use, disposition, and disclosure of data will not be made without the written informed consent of the appropriate individual. In all cases, Personally Identifiable and Confidential Health Information shall not be disclosed unless the identification is essential in order to achieve the purpose for which the information is sought or if preventing the identification would clearly be impractical, but not if the subject of the information is likely to be harmed by the identification.
   d. A recipient or any other person acting on a recipient's behalf may file a recipient rights complaint with the Office of Recipient Rights alleging a violation of the recipient's rights as a human research subject.

5. Individuals or entities approved to conduct research who are not already employees, contract employees, or volunteers shall be considered volunteers, and shall be subject to all and applicable workforce standards, including background checks, applicable training requirements, and Northern Lakes CMHA policies and procedures.

Procedures

1. All proposals for research on human subjects shall be presented in writing to the Northern Lakes CMHA Chief Executive Officer.

2. The Chief Executive Officer shall bring the proposal to the Northern Lakes CMHA Executive Team for review.

3. The Executive Team shall assure that the Recipient Rights Officer and the Compliance Officer are informed, in a timely manner, of the proposed research and are consulted thereafter regarding any issues appropriate to their respective areas of authority.

4. The individual or entity proposing to conduct Human Subjects Research is solely responsible for securing approval of the research protocol by the MDHHS IRB. The instructions and application form are available from the MDHHS website or can be requested by calling 517-241-1928. Two printed signed copies of the application, and any other material required by the application should be sent, at least two weeks before the first Tuesday of each month to:

   MDHHS Institutional Review Board
   South Grand Building, 5th Floor
   333 South Grand Avenue
   PO Box 30195
   Lansing, MI 48909

5. If approved by the IRB and the Executive Team, researchers shall be required to do all of the following:
   a. Execute a Northern Lakes CMHA confidentiality agreement; and
   b. If not already an employee or contract provider, to pass a background check of the same scope and utilizing the same standards as for Northern Lakes CMHA employees;
   c. Receive Northern Lakes CMHA training as deemed appropriate to the proposed research including Recipient Rights training within 30 days of approval;
   d. Provide, in an manner understandable to the recipient or his/her legally empowered representative, an explanation of the rights of the subject of the research;
   e. Obtain written informed consent from the recipient or his/her legally empowered representative with respect to the proposed research.
   f. Ensure that no changes to the study are implemented after approval by the IRB (except when necessary to eliminate an apparent immediate hazard to the subject);
   g. Immediately report to the Northern Lakes CMHA Executive Team any unexpected problems that could potentially be an apparent or potential hazard or risk to the human subject;
   h. Exclude all Personally Identifiable and Confidential Health Information from the results of the research prior to reporting any findings;
   i. Not to use any Personally Identifiable and Confidential Health Information acquired or created in the course of the research project for any purpose not specified in the Research Protocol;
   j. Store Personally Identifiable and Confidential Health Information in hard copy format acquired or created in the course of the research only within the physical confines of a facility owned or operated by Northern Lakes CMHA or a facility operated by a member of the Northern Lakes CMHA Provider Network;
   k. Store Personally Identifiable and Confidential Health Information in electronic format acquired or created in the course of the research only on media and systems physically situated within the confines of a facility owned or operated by Northern Lakes CMHA;
   l. Submit the proposed final report to the Executive Team review prior to the its submission to the project sponsor;
   m. Provide the Executive Team with a copy of the final report within 7 calendar days of its acceptance by the project sponsor;
   n. Within 21 calendar days of the acceptance of the final report, to certify to the CEO that all Personally Identifiable and Confidential Health Information in any format or

medium acquired or created by the researchers in the course of the research project has been returned to Northern Lakes CMHA or destroyed; and

o. Pay Northern Lakes CMHA a royalty of not less than 1% of gross sales arising from commercial publication and distribution of the Final Report in any medium.

6. Completed Research Project Record Retention:
Northern Lakes CMHA shall maintain a hard copy of all correspondence and documents (including printouts of e-mails) related to the approval and conduct of the research project in a single project file until research project is completed. Following completion, the project file shall be retained with other completed project files for a period of not less than 7 years from the date of completion, after which the file shall be destroyed.

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