
PROCEDURE 2513-A**General**

When the North Sound Mental Health Administration (NSMHA) uses or discloses an Individual's information for research purposes, NSMHA must consider the following:

1. NSMHA may use or disclose an Individual's information for research purposes as specified in this policy.
2. All such research disclosures are subject to applicable requirements of state and federal laws and regulations and to the specific requirements of this policy. Note: This policy is intended to supplement existing research requirements of the Common Rule, 45 CFR Part 46. The Common Rule is the rule for the protection of human subjects in research promulgated by the U.S. Department of Health and Human Services, and adopted by other federal governmental agencies, including the National Institutes for Health, for research funded by those agencies. In addition, some agencies have requirements that supplement the Common Rule that are applicable to a particular research contract or grant.
3. De-identified information may be used or disclosed for purposes of research, consistent with NSMHA's Policy for De-Identification of Patient Information.
4. NSMHA may also conduct public health studies, studies that are required by law, and studies or analysis related to its health care operations.

Institutional Review Board (IRB) or Privacy Board established by NSMHA

NSMHA may use an IRB established in accordance with 45 CFR Part 46 or a Privacy Board that has been established by NSMHA pursuant to this policy, to perform the duties and functions specified in this policy regarding a research project being conducted, in whole or in part, by NSMHA or by a NSMHA office or program.

Uses and Disclosures for Research Purposes – Specific Requirements

NSMHA may use or disclose patient or participant information for research purposes with the patient's specific written authorization.

Such authorization must meet all NSMHA's uses and disclosure requirements and may indicate as an expiration date such terms as "end of research study," or similar language.

An authorization for use and disclosure for a research study may be combined with any other type of written permission for the same research study.

If research includes treatment, the researcher may condition the provision of research related treatment on the provision of an authorization for use and disclosure for such research.

NSMHA may use or disclose patient or participant information for research purposes without the patient's or participant's written authorization, provided that:

NSMHA obtains documentation that a waiver of an Individual's authorization for release of information requirements has been approved by either:

1. An IRB; or
2. A Privacy Board that:

- a. Has members with varying backgrounds and appropriate professional competency as needed to review the effect of the research protocol on the Individual's privacy rights and related concerns;
- b. Includes at least one member who is not affiliated with NSMHA, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any such entity; and
- c. Does not have any member participating in a review of any project in which the member has a conflict of interest.

Documentation required of IRB or privacy board when granting approval of a waiver of an individual's authorization for release of information must include:

1. A statement identifying the IRB or Privacy Board that approved the waiver of an Individual's authorization, and the date of such approval;
2. A statement that the IRB or Privacy Board has determined that the waiver of authorization, in whole or in part, satisfies the following criteria:
 - a. The use or disclosure of an Individual's protected information involves no more than minimal risk to the privacy of individuals, based on at least the following elements:
 - i. An adequate plan to protect an Individual's identifying information from improper use or disclosure;
 - ii. An adequate plan to destroy an Individual's identifying information at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
 - iii. Adequate written assurances that the Protected Health Information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the protected information would be permitted under this policy;
 - b. The research could not practicably be conducted without the waiver, and;
 - c. The research could not practicably be conducted without access to and use of the Individual's protected information.
 - d. A brief description of the Protected Health Information for which use or disclosure has been determined to be necessary by the IRB or Privacy Board;
 - e. A statement that the waiver of an Individual's authorization has been reviewed and approved under either normal or expedited review procedures, by either an IRB or a Privacy Board, pursuant to federal regulations at 45 CFR 164.512(2); and the Privacy Board Chair must sign documentation of the waiver of an Individual's authorization, or other member as designated by the Chair of the IRB or the Privacy Board, as applicable.

In some cases, a researcher may request access to individual information maintained by NSMHA in preparation for research or to facilitate the development of a research protocol in anticipation of research. Before agreeing to provide such access to individual information, NSMHA should determine whether federal or state law otherwise permits such use or disclosure without the Individual's authorization or the use of an IRB. If there is any doubt whether the use and disclosure of the information by the researcher falls within this Health Insurance Portability and Accountability Act (HIPAA) exception, review by an IRB or Privacy Board and formal waiver of authorization is required.

If such access falls within this HIPAA exception to authorization and is otherwise permitted by other federal or state law, NSMHA will only provide such access if NSMHA obtains, from the researcher, written representations that:

1. Use or disclosure is sought solely to review an Individual's protected information needed to prepare a research protocol or for similar purposes to prepare for the research project;
2. No patient information will be removed from NSMHA by the researcher in the course of the review;
3. The patient information for which use or access is sought is necessary for the research purposes;
4. The researcher and his or her agents agree not to use or further disclose the information other than as provided in the written agreement, and to use appropriate safeguards to prevent the use or disclosure of the information other than is provided for by the written agreement;
5. The researcher and his or her agents agree not to publicly identify the information or contact the individual whose data is being disclosed; and
6. Applicable federal or state law may require such other terms or conditions.

In some cases, a researcher may request access to individual information maintained by NSMHA about individuals who are deceased. NSMHA should determine whether federal or state law otherwise permits such use or disclosure of information about decedents without individual authorization or use of an IRB. There may be instances where it would be inappropriate to disclose information, even where the individual subject of the information is dead – for example, individuals who died of AIDS may not have wanted such information to be disclosed after their deaths.

If there is any doubt whether the use and disclosure of the information by the researcher falls within this HIPAA exception, review by an IRB or Privacy Board and formal waiver of authorization is required. If such access falls within this HIPAA exception to authorization and is otherwise permitted by other federal or state law, NSMHA will only provide such access if NSMHA obtains the following written representations from the researcher:

1. A representation that the use or disclosure is sought solely for research on the protected information of deceased persons;
2. Documentation, if NSMHA so requests, of the death of such person(s);
3. A representation that the Individual's protected information for which use or disclosure is sought is necessary for the research purposes;
4. The researcher and his or her agents agree not to use or further disclose the information other than as provided in the written agreement, and to use appropriate safeguards to prevent the use or disclosure of the information other than is provided for by the written agreement;
5. The researcher and his or her agents agree not to publicly identify the information or contact the personal representative or family members of the decedent; and
6. Applicable federal or state law may require such other terms or conditions.

NSMHA Public Health Studies and Studies Required by Law

When NSMHA is operating as a Public Health Authority, NSMHA is authorized to obtain and use individual information without authorization for the purpose of preventing injury or controlling disease and for the conduct of public health surveillance, investigations and interventions. In addition to these responsibilities, NSMHA may collect, use or disclose information, without individual authorization, to the extent that such collection, use or disclosure is required by law. When NSMHA uses information to conduct studies pursuant to such authority, no additional individual authorization is required, nor does this policy require IRB or Privacy Board waiver of authorization based on the HIPAA Privacy rules. Other applicable laws and protocols continue to apply to such studies.

NSMHA Studies Related to Health Care Operations

Studies and data analyses conducted for NSMHA's own quality assurance purposes and to comply with reporting requirements applicable to federal or state funding requirements fall within the uses and disclosures that may be made without individual authorization as NSMHA health care operations. Neither individual authorization nor IRB or Privacy Board waiver of authorization is required for studies or data analyses conducted by or on behalf of NSMHA for purposes of health care operations, including any studies or analyses conducted to comply with reporting requirements applicable to federal or state funding requirements. "Health care operations" as defined in 45 CFR 164.512, include:

1. Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities;
2. Conducting population-based activities relating to improving health care or reducing health care costs, protocol development, case management and care coordination, contacting health care providers and patients with information about treatment alternatives and related functions that do not include treatment;
3. Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, and conducting training programs, and accreditation, certification, licensing or credentialing activities;
4. Underwriting, premium rating, and other activities related to the creation, renewal or replacement of a contract of health insurance or health benefits;
5. Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;
6. Business planning and development, such as conducting cost-management and planning related analyses related to managing and operating NSMHA, including improvement of administration or development or improvement of methods of payment or coverage policies;
7. Business management and general administrative activities of NSMHA, including management activities related to HIPAA implementation and compliance; customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers; resolution of internal grievances; and
8. Creating de-identified information or a limited data set consistent with NSMHA policies.

Exception: HIV-AIDS information may not be disclosed to anyone without the specific written authorization of the Individual. Re-disclosure of HIV test information is prohibited, except in compliance with law or with written permission from the Individual.

Enforcement

NSMHA's Privacy Officer and supervisors are responsible for enforcing this policy. Individuals who violate this policy are subject to disciplinary action, up to and including termination or dismissal.