Effective Date: 7/1/2019
Review Date: 2/25/2025
Revised Date: 2/25/2025

North Sound Behavioral Health Administrative Services Organization, LLC

Section 2500 – Privacy: Research

Authorizing Source: 45 CFR 164.512 (HIPAA); 42 CFR Part 2 (Part 2); 42 CFR Part 46 (Human Subject Research); RCW 70.02
Approved by: Executive Director Date: 2/25/2025 Signature:

POLICY # 2513.00

SUBJECT: Research

PURPOSE

In compliance with the Health Insurance Portability and Accountability Act (HIPAA), Part 2, the federal Human Subject Research Regulations and State Law, this policy addresses the Use or Disclosure of Protected Health Information (PHI) for Research purposes.

Capitalized terms have special meanings. Definitions under this policy include De-Identified Data, Health Care Operations, Human Subject Research Regulations, Individual, Institutional Review Board (IRB), Limited Data Sets, Mental Health Information, Part 2 Information, Part 2 Program, Privacy Board, Protected Health Information (PHI), Research, Sexually Transmitted Disease (STD), Treatment and Workforce. See Policy 2502.00: Definitions for Policies Governing PHI.

POLICY

North Sound Behavioral Health Administrative Services Organization (North Sound BH-ASO) will Use and Disclose PHI for Research only in accordance with this policy and as permitted by HIPAA, Part 2, the Human Subject Regulations and State Law.

PROCEDURES

1. **General Research Requirements.**

   1.1 **Definition of Research.** Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Research does not include Use of PHI strictly for Health Care Operations (for example, quality improvement and outcomes analysis purposes). Workforce members who are uncertain about whether a particular study or activity qualifies as Research should contact the Privacy Officer.

   1.2 **Uses and Disclosures of PHI for Research.** PHI may be Used or Disclosed for Research purposes only with valid authorization by, or on behalf of, the Individual (see Section 3 of this policy) or as otherwise permitted by law and this policy (see Section 2 of this policy). Note: There are special requirements for Use and Disclosure of Part 2 Information for Research purposes (see Section 4 of this Policy). A Workforce member must have the approval of the Privacy Officer before any PHI may be Used or Disclosed for Research purposes.

1.3 **Other Research Situations.** Use and Disclosure of PHI for Research purposes may be permissible under circumstances other than as described in this policy but only with the Privacy Officer's advance approval.

1.4 **Timing of Access for Research.** A researcher must obtain authorization by or on behalf of the Individual or a waiver of authorization from the IRB or Privacy Board and approval of the Privacy Officer before receiving access to any PHI for the intended Research.

2. **Research Use or Disclosure Without Individual Authorization.** A Workforce member may Use or Disclose PHI for Research purposes without a written authorization under the circumstances described below. In each case, the Use or Disclosure requires prior written approval by an IRB or Privacy Board that is designated or recognized by North Sound BH-ASO and the Privacy Officer and only to the extent that recipient needs to know the PHI.

2.1 **Alteration to or Waiver of Authorization.**

2.1.1 General. A Workforce member may Use or Disclose PHI for Research without a written authorization if an IRB or Privacy Board has approved an alteration to or waiver, in whole or in part, of the authorization requirement, as set forth in this Section.

2.1.2 Application. Applications for waiver or partial waiver of authorization must identify specifically what information in the records about Individuals will be reviewed if the waiver is approved and must request the minimum necessary amount of PHI consistent with Policy 2509.00: Minimum Necessary.

2.1.3 Approval Requirements. The IRB or Privacy Board may approve a waiver of authorization if:

(a) The Disclosure is of sufficient importance to outweigh the intrusion into the privacy of the Individual that would result from the Disclosure. (Note: this is a requirement based on State Law).

(b) The Use or Disclosure of PHI involves no more than a minimal risk to the privacy of Individuals, based on at least the presence of all of the following:

i. An adequate plan to protect the identifiers from improper Use, Disclosure and redisclosure;

ii. Reasonable safeguards to protect against identifying, directly or indirectly, any Individual in any report of the Research project;

iii. An adequate plan to destroy the identifiers at the earliest opportunity, consistent with the conduct of the Research, unless there is a health or Research justification for retaining the identifiers or retention is Required by Law; and

iv. Adequate written assurances the PHI will not be reused, or Disclosed to any other Person, except as Required by Law, for authorized oversight of the Research project or for other Research for which the Use or Disclosure of PHI would be permitted by law. **Note: Part 2 Information may not be reused or redisclosed**.

(c) The Research could not practicably be conducted without the waiver or alteration.
(d) The Research could not practicably be conducted without access to and Use of the PHI.
(e) The waiver or alteration will not adversely affect the rights and welfare of the Individuals.
(f) Whenever appropriate, the Individuals will be provided with additional pertinent information after participation.

2.1.4 IRB or Privacy Board Review and Documentation. The IRB or Privacy Board is required to review and act upon any request submitted for approval of an alteration to or waiver of authorization for Research. A Workforce member seeking to Use or Disclose PHI for Research may request a waiver of authorization for a segment of a study population, such as when requesting to Use records for the study control group or for the whole study population. Any alteration to or waiver of authorization granted by the IRB or Privacy Board must include the following:

(a) Identification of the IRB or Privacy Board and the date on which the alteration or waiver of authorization was approved;
(b) A statement that the IRB or Privacy Board has determined the alteration or waiver of authorization, in whole or in part, satisfies the requirements under Section 2.1.3 of this policy;
(c) A brief description of the PHI for which Use or access has been determined to be necessary by the IRB or Privacy Board;
(d) A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures; and
(e) The signature of the chair or other member, as designated by the chair, of the IRB or Privacy Board.

2.1.5 Privacy Officer Approval. If the IRB or Privacy Board approves an alteration or waiver of authorization, then the Workforce member will obtain the Privacy Officer's approval before the Workforce member may Use or Disclose PHI for Research purposes.

3. **Research Use and Disclosure with Individual Authorization.** A Workforce member may Use and Disclose PHI for Research purposes to the extent the Individual or the Individual's Authorized Representative has provided a written valid authorization, as set forth in this section.

3.1 **Research Authorizations.**

3.1.1 Requirements. The authorization must meet all requirements under HIPAA, Part 2, the Human Subject Regulations, State Law and North Sound BH-ASO Policy 2521.00: Authorization for Use and Disclosure of PHI.

3.1.2 Special Characteristics**.**

(a) An authorization for Research may state, as applicable, that: the authorization does not expire; there is no expiration date or event; or the authorization continues until the end of the Research study.

(b) An authorization may be combined with a consent to participate in the Research or with any other legal permission related to the Research study.

(c) For Research authorizations that include Treatment of the Individual as part of the Research, the authorization must include a statement that the provision of Research-related Treatment is conditioned upon receiving an authorization for the Use and Disclosure of PHI for the Research.

(d) If an authorization is combined with an authorization for another Research study or activity (such as an authorization to maintain PHI in a Research database or repository) and the other authorization is not a condition of Treatment, then the combined authorization must clearly differentiate between the conditioned and unconditioned components and must provide the Individual with an opportunity to opt in to the unconditioned authorization (e.g., to opt in to the Research database or repository).

(e) Although an Individual has a general right to revoke an authorization, North Sound BH-ASO may continue to Use or Disclose PHI after an Individual has revoked an authorization to the extent North Sound BH-ASO previously has taken actions in reliance on the authorization. For Research purposes, this exception permits Workforce members conducting Research to continue to Use and Disclose PHI already obtained through a valid authorization to the extent necessary to preserve the integrity of the Research study. For example, this exception would permit the continued Use and Disclosure of PHI:

i. To account for an Individual's withdrawal from the Research study;
ii. As necessary to incorporate the PHI as part of a marketing application submitted to the U.S. Food and Drug Administration;
iii. To conduct investigations of scientific misconduct; or
iv. To report adverse events as required by the IRB or Privacy Board or as Required by Law.

(f) Note: For clarity, authorization requirements apply to Use and Disclosure of PHI for the creation and maintenance of a Research database or Research repository, collection of PHI with data or tissue specimens for Research purposes and any other Uses and Disclosures of PHI for Research purposes, unless otherwise specified under this policy.

3.2 **Disclosure of PHI for Research Conducted Outside of North Sound BH-ASO.** North Sound BH-ASO may rely upon an authorization signed by or on behalf of the Individual to Disclose PHI for Research activities conducted outside of North Sound BH-ASO, as long as the Privacy Officer reviews the authorization and verifies the following:

3.2.1 Validity. The authorization is valid as described in this policy and Policy 2521.00: Authorization for Use and Disclosure of PHI;

3.2.2 Permission to North Sound BH-ASO. The authorization authorizes North Sound BH-ASO to Use or Disclose the PHI requested for the Research study; and

3.2.3 Limited Disclosure. North Sound BH-ASO Discloses no more PHI than what is authorized by or on behalf of the Individual under the terms of the authorization.

4. Research Related to Part 2 Information.

4.1 **Disclosures of Part 2 Information for Research.** North Sound BH-ASO, as a Lawful Holder of Part 2 Information, or a Part 2 Program may Disclose Part 2 Information for the purpose of Research if the Privacy Officer and the director, managing director, chief executive officer or designee makes one of the following determinations:

4.1.1 If the researcher is a Covered Entity or Business Associate, then the researcher has obtained and documented an authorization from or on behalf of the Individual or a waiver or alteration as required by HIPAA and as described in Section 3 of this policy; and

4.1.2 If the researcher both is a Covered Entity or Business Associate and is subject to the Human Subject Research Regulations, then the researcher has met the requirements of both Sections 4.1.1 and 4.2 of this policy.

4.2 **Compliance with Human Subject Research Regulations.** If the Research study is subject to the Human Subject Research Regulations, then North Sound BH-ASO must obtain from the researcher the researcher's documentation that either the researcher is in compliance with these requirements, including the requirements related to informed consent or a waiver of consent, or the Research qualifies for exemption under these requirements.

4.3 **Obligations of Researcher Using Part 2 Information.** Any Person conducting Research using Part 2 Information must agree, in writing, that the Person:

4.3.1 Is fully bound by Part 2 and, if necessary, will resist in judicial proceedings any efforts to obtain access to Part 2 Information except as permitted by Part 2;

4.3.2 Must not redisclose Part 2 Information except back to the Part 2 Program or as permitted for data linkage purposes (see Section 4.4 of this policy);

4.3.3 May include Part 2 Information in Research reports only in aggregate form in which Part 2 Information has been rendered non-identifiable and De-Identified so the information cannot be re-identified and serve as an unauthorized means to identify an Individual, directly or indirectly, as having or having had a Substance Use Disorder (SUD);

4.3.4 Must maintain appropriate safeguards and destruction practices and destroy Part 2 Information in accordance with requirements established by Part 2 and HIPAA; and

4.3.5 Must retain records in compliance with applicable federal, state and local record retention laws.

4.4 **Data Linkage.**

4.4.1 Any person or entity conducting Research using Part 2 Information that requests linkages to data sets from a data repository holding Part 2 Information must:

(a) Have the request reviewed and approved by an IRB so that Individual privacy is considered and the need for identifiable data is justified. Upon request, the researcher may be required to provide evidence of the IRB approval of the Research project that contains the data linkage component; and
(b) Not provide the Part 2 Information to Law Enforcement Officials or agencies.

4.5 **Data Repositories.** Data repositories are fully bound by Part 2 upon receipt of Part 2 Information and must:

4.5.1 After providing the researcher with the linked data, destroy or delete the linked data from its records, including sanitizing any associated hard copy or electronic media, to render the Part 2 Information non-retrievable in a manner consistent with HIPAA, Part 2 and State Law;
4.5.2 Not redisclose Part 2 Information for data linkage purposes other than as provided for in this section 4.5; and
4.5.2 Not provide the Part 2 Information to Law Enforcement Officials or agencies.

5. **Other Requirements Related to Research.**

5.1 **Individual's Right of Access to PHI.** North Sound BH-ASO will provide access to PHI Used in Research in accordance with Policy 2514.00: Right to Access to PHI. Note: There may be situations in which access to PHI used for Research purposes may be delayed.

5.2 **Accounting for Disclosures.**

5.2.1 General Requirements. North Sound BH-ASO will comply with all requirements set forth in Policy 2516.00: Right to Accounting of Disclosures. Any Use or Disclosure of PHI for Research purposes that is not for Treatment, Payment or Health Care Operations or specifically authorized by the Individual will be recorded and included in an accounting.
5.2.2 Simplified Accounting. If a Disclosure made for Research purposes involved records of fifty (50) or more Individuals, then a simplified accounting is permitted. The simplified accounting will provide:

(a) The name of the protocol or other Research activity;
(b) A description, in plain language, of the Research protocol or other Research activity, including the purpose of the Research and the criteria for selecting particular records;
(c) A brief description of the type of PHI that was Disclosed;
(d) The date or timeframe during which the Disclosures occurred, or may have occurred, including the date of the last Disclosure during the accounting period;

(a) The name, address and telephone number of the entity that sponsored the Research and of the researcher to whom the information was Disclosed; and
(b) A statement that the PHI about the Individual may or may not have been Disclosed for a particular protocol or other Research activity.

If an accounting for Research Disclosures is made under this Section and if it is reasonably likely that PHI about the Individual was Disclosed for the Research protocol or activity, then the Privacy Officer, at the written request of the Individual, will assist in contacting the entity that sponsored the Research and the researcher.

5.2.3 North Sound BH-ASO Research. Researchers who access PHI through North Sound BH-ASO must provide detailed information regarding the PHI that is to be accessed to allow North Sound BH-ASO to meet its obligations to provide Individuals with an accounting of Disclosures of the PHI as Required by Law.

5.3 **Minimum Necessary.** Workforce members will comply with Policy 2509.00: Minimum Necessary with respect to requests for and Uses and Disclosures of PHI for Research purposes.

6. **Research Involving De-Identified Data.** De-Identified Data (that satisfies the requirements under Policy 2503.00: De-Identified Data and Limited Data Sets) may be requested for Research purposes, including to determine the feasibility of the Research study. Any request for De-Identified Data will be submitted or forwarded to the Privacy Officer.

7. **Limited Data Sets with Data Use Agreement.** A Limited Data Set may be Used for Research, in accordance with the requirements of Policy 2503.00: De-Identified Data and Limited Data Sets. These requirements include having the recipient of the Limited Data Set enter into a valid Data Use Agreement before being permitted to receive, access, Use or Disclose the Limited Data Set.

8. **North Sound BH-ASO Public Health Studies and Studies Required by Law.** When North Sound BH-ASO is operating as a Public Health Authority, it will abide by all federal and state Research requirements as detailed in this policy and to the extent permitted, North Sound BH-ASO is authorized to obtain and Use certain Individual information without authorization for the purpose of preventing injury or controlling disease and to conduct of public health surveillance, investigation and interventions. In addition to these responsibilities, North Sound BH-ASO may collect, Use and Disclose PHI, without Individual authorization, to the extent the collection, Use and Disclosure is Required by Law. Other applicable laws and protocols continue to apply to these studies.

9. **Documentation.** Documentation relating to Research shall be retained at least six (6) years from the time that the document last was in effect. Retention requirements include, but are not limited to:

9.1 **Research policies and procedures.**
9.2 **IRB waivers and partial waivers.**
9.3 **Information concerning particular Research studies.**
9.4 **Authorization and consent forms.**

10. **Related Policies.** Other policies and procedures to review that are related to this policy:

10.1 **Policy 2501.00: Privacy and Confidentiality of PHI.**
10.2 **Policy 2502.00: Definitions for Policies Governing PHI.**
10.3 **Policy 2503.00: De-Identified Data and Limited Data Sets.**
10.4 **Policy 2509.00: Minimum Necessary.**
10.5 **Policy 2514.00: Right to Access PHI.**
10.6 **Policy 2516: Right to Accounting of Disclosures.**
10.7 **Policy 2521.00: Authorization for Use and Disclosure of PHI.**

ATTACHMENTS
None