

**Nova Southeastern University
HIPAA Policy
Research**

Research Uses and Disclosures Policy and Procedure

Policy:

1. Applicability of Research Policy

The new federal privacy regulations implementing the Health Insurance Portability and Accountability Act (HIPAA) of 1996 went into effect April 14, 2003. The privacy regulations set forth requirements for the use and disclosure of protected health information (PHI) in research.

Regardless of the relationship of the NSU researcher to NSU (e.g., faculty, adjunct, staff, student, resident or fellow) and to other entities outside of NSU (e.g., faculty and/or student at a teaching affiliate site), the NSU researcher must follow the procedures of the entity where the PHI will be obtained.

Researchers must refer to this policy to determine their responsibilities related to HIPAA compliance. Researchers will have other responsibilities related to human subject research, including compliance with the Common Rule. In addition to this policy, researchers will need to consult with NSU's IRB policies and procedures related to the Common Rule to determine when and how to obtain IRB approval for a project and when and how to obtain informed consent.

2. What is Protected Health Information (PHI)?

2.1 PHI is health information transmitted or maintained in any form or medium that:

- identifies or could identify an individual; and
- is created or received by a healthcare provider, health plan, employer or healthcare clearinghouse; and
- relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual.

2.2 The sources of PHI may include the following:

- PHI utilized for review preparatory to research to determine whether or not to begin a study; and
- PHI stored in databases or repositories (e.g., a health care provider or hospital patient database); and
- PHI relating to living participants; and
- PHI relating to human tissue samples; and
- PHI relating to deceased persons.

2.3 Health-related information is not considered PHI if the researcher obtains it from:

- student records maintained by a school; or
- employee records maintained by an employer related to employment status

3. **General Rule Related to Research Uses and Disclosures**

3.1 General Rule: Need patient Authorization:

As a general rule, authorization is required for uses and disclosures related to research. Absent a waiver of authorization (discussed below) human subjects research participation at NSU will require that each subject sign a NSU IRB approved research consent/authorization form. This form may either combine the elements of consent and authorization or may separate these elements.

3.2 Authorization Contents:

To be valid, an authorization for research must include all of the following:

1. A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.
2. Name or specific identification of the person or persons who can make the requested use or disclosures (e.g., NSU clinic).
3. Name or specific identification of the person or persons who may receive the requested use or disclosures (e.g., the researcher or study sponsor).
4. A description of each purpose of the requested use or disclosure (e.g., the name of the research study).
5. An expiration date or event, or can use “no expiration” since the authorization is for research.
6. Statement of the individual’s right to revoke authorization in writing, exceptions to the right to revoke, and description informing the patient how to revoke the authorization (including a reference to the Notice of Privacy Practices).
7. The consequences, if any, that will result from the patient’s refusal to sign, including a statement that NSU may not condition treatment on the patient’s willingness to sign the authorization (except for treatment that is part of the research project).
8. A statement that information used or disclosed may be subject to re-disclosure by the recipient and no longer protected by the HIPAA rule.
9. The patient’s (or personal representative’s) signature and date signed.
10. If signed by a personal representative, a description of the representative’s authority to act on behalf of the individual.

3.3 The Authorization contents listed in Section 3.2 shall be included within the Informed Consent approved by the IRB.

- 3.4 The authorization form must be kept in the patient's research chart and/or research section of the patient record for at least six (6) years. The patient should also be provided with a copy of the signed authorization form.
- 3.5 The IRB is responsible for reviewing the contents and compliance of an authorization as part of the study's informed consent document.

4. When Authorization Is Not Needed: 4 Key Exceptions

Authorization is not needed in the following limited circumstances:

- IRB Waiver
- De-identified information
- Reviews Preparatory to Research
- Research on a Decedent's Information

4.1 IRB Waiver of Authorization

- Authorization is not required if there is a documented waiver of authorization from the IRB. However, the accounting of disclosures form for research will need to be completed for this disclosure, in accordance with Section 5 of this Policy.
- A researcher may request a waiver of authorization by going through the IRB. The IRB Board can grant a waiver of the authorization requirement if the following is documented and approved through full review of the IRB.
 1. A statement identifying the IRB and the date on which the waiver of authorization was approved.
 2. A statement that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals because:
 - a. There is an adequate plan to protect the identifiable information from improper use and disclosure,
 - b. There is an adequate plan to destroy identifiers at the earliest opportunity consistent with 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
 - c. 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 protected health information would be permitted by this subpart.
 3. A statement that the research could not be conducted without the waiver.
 4. A statement that the research could not be conducted without access to and use of the protected health information.

5. A brief description of the protected health information that is needed for the study.
 6. A statement that the waiver has been reviewed by the IRB under full review procedures.
 7. All alternative methods of conducting the study have been exhausted.
- All waiver requests should be submitted through the standard IRB procedures.
 - It is the responsibility of all researchers to comply with this policy.

4.2 De-Identified Information Without Authorization

- Information may be used by a researcher or disclosed to a researcher without authorization if the information has been de-identified by an employee of the NSU Health Care Center/Clinic prior to the disclosure. In order to be considered de-identified, **all** of the following must be removed:
 - Names
 - Geographic subdivisions smaller than a state (in certain circumstances, the first 3 digits of a zip code can be used)
 - All elements of dates (except year) for dates directly related to an individual
 - All ages or dates indicating an age over 89 (they can be lumped into one category of 90 or older)
 - Telephone numbers
 - Fax numbers
 - Social security number
 - Medical record numbers
 - Health plan beneficiary numbers
 - Account numbers
 - Certificate/license numbers
 - Vehicle identifiers and serial numbers
 - Web universal resource locators (URLs)
 - Internet Protocol (IP) address numbers
 - Biometric identifiers, including finger and voice prints
 - Full face photographic images and any comparable images
 - Any other unique identifying number, characteristic or code
- Re-identification codes may be randomly assigned as long as the re-identification key is retained and safeguarded by the NSU Health Care Center/Clinic.
- The de-identified research must be reviewed by the IRB prior to conducting the research.

4.3 Reviews Preparatory to Research Without Authorization

- Researchers are required to receive approval from the IRB prior to commencement of his/her review preparatory to research.
- Authorization is not required if the information is being gathered or used in preparation for research (for example, to identify potential research subjects or populations) as long as the uses and disclosures are necessary to the research and the information does not leave the NSU Health Care Center/Clinics or covered entity. Please note accounting of disclosure forms will also need to be completed for these records (See Section 5 of this Policy).
- Researchers may review records “preparatory to research”, including reviews of records to develop a protocol or determine the feasibility of a research study, under the following circumstances:
 - The use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research
 - No protected health information is to be removed from the health care center/clinic by the researcher in the course of review
 - The protected health information is necessary for the research purposes
- If a researcher performs reviews preparatory to research, he or she cannot directly contact patients about the study, unless he/she is the patient’s health care provider and/or member of the clinic workforce. The health care provider and/or clinic personnel may give patients the name and telephone number of the researcher.

4.4 Research on Decedent’s Information Without Authorization

- Authorization is not required for research if the patient is deceased, the use or disclosure is solely for research and is necessary to the research. Note that accounting of disclosure form must be completed for these disclosures, see Section 5 of this Policy.
- Researchers may use and disclose the records of deceased patients for research purposes without obtaining authorization from a personal representative under the following circumstances:
 - The use or disclosure sought is solely for research on the protected health information of the decedent
 - There is documentation of the death of the patients in question
 - The protected health information for which use or disclosure is sought is necessary for the research purposes
 - The research must be approved by the IRB.

5. Accounting of Disclosures

- If a researcher reviews patient records and these reviews are conducted without a HIPAA compliant authorization (e.g. reviews preparatory to research or with a waiver from the IRB), then the researcher must keep a list of all patient records that were reviewed, the dates on which the records were reviewed, and a description of the type of information that was reviewed (e.g., diagnosis or procedure code).
- This information should be kept on an Accounting of Disclosures for Research Form and must be provided to the clinic's Privacy Contact **for placement in the patient's chart. (Please see sample Accounting of Disclosure for Research Form)**
- If multiple patient records are being reviewed for the same research protocol, the researcher may complete the entire form, with the exception of patient name and make photocopies of the form. The researcher will then need to print the name, SSN, and/or birth date of each patient record that is reviewed on the forms.

6. Responsibility of NSU Clinics for Accounting of Disclosures

- It will be the responsibility of the researcher to complete the Accounting of Disclosures for Research Form and provide it to the Privacy Contact.
- When a patient asks for an accounting of his or her disclosures, it will be the responsibility of the Privacy Contact to compile the information contained on all "Accounting of Disclosures for Research Forms" as well as on the "Accounting of Disclosures Form" for those disclosures made subject to Policy 3B (uses and disclosures for special circumstances, such as for disclosures required by law or for health oversight).
- As set forth in Policy 3B of the clinic policies, the clinic has sixty (60) days to provide the information. The clinic can obtain an extension of up to thirty (30) days per request by notifying the patient of the reason for delay and the estimated completion date.
- The patient's first accounting during a twelve (12) month period must be provided free of charge. If the patient requests more than one accounting of disclosures within a twelve (12) month period, the clinic can impose a reasonable cost-based charge. If a charge is imposed, the patient must be informed of the charge and given an opportunity to withdraw his or her request.
- Information on disclosures that are subject to the accounting and documentation that is provided to the patient must be kept for a period of at least six (6) years.

7. Revocation of Authorization

- An individual can revoke an authorization in writing at any time. All research authorizations will contain a statement alerting the patient that he or she may revoke the authorization by contacting the researcher.
- If a researcher receives a request for revocation of authorization by the patient, it will be the researcher's responsibility to stop all future uses and disclosures of the patient's information for research purposes.
- It is also the researcher's responsibility to notify the clinic's Privacy Contact if the research information is contained in the clinic chart.

8. Research and Record Reviews Conducted at Entities Outside of NSU

- If the protected health information was created or maintained by a covered entity outside of NSU, then the NSU faculty, adjunct, staff, student, resident, or fellow is required to follow all research and HIPAA policies of the hospitals, clinics, facilities and/or other covered entities at which he/she has access to protected health information.
- NSU students, faculty and employees have an affirmative duty to request information on research and HIPAA policies from the entity's Privacy Officer and IRB prior to conducting any type of patient record review or research.

9. Education vs. Research Guidance

- 9.1 The HIPAA Privacy Rule defines research as “a systematic investigation, including research development, testing, and evaluation, *designed to develop or contribute to generalizable knowledge.*”
- 9.2 The scope of the NSU Institutional Review Board's responsibilities is broad. Generally, any NSU research that uses humans, human tissue, surveys of human subjects, or human subjects records requires IRB review, irrespective of the funding source. The IRB's responsibilities extend to research in the social and behavioral sciences as well as research in the health and biological sciences.
- 9.3 The following are examples of some indicators that a project falls within the definition of **research and requires IRB review**:
- ❖ The activity is designed to test a hypothesis or permit conclusions to be drawn
 - ❖ The information is being gathered as part of a formal protocol that sets forth an objective and a set of procedures designed to reach that objective
 - ❖ The information is being gathered to create a data base or research repository for future research

- ❖ Courses in research methods and class assignments that involve research with humans, human tissue, surveys of human subjects, or human subjects records require IRB approval. The IRB reviews research for risk assessment and provisions for informed consent.
 - ❖ For a NSU researcher to participate in a research project at another site, the project needs to be reviewed by NSU as well as the other institution's IRB.
- 9.4 For further guidance in determining whether an activity constitutes “research”, individuals should contact the IRB.
- 9.5 Examples of uses/disclosures that would be considered educational purposes and **not research** would include:
- ❖ De-identified information used/disclosed for review of a student's performance
 - ❖ De-identified information used/disclosed for classroom activities within NSU
 - ❖ De-identified information used/disclosed for current or future teaching activities within NSU
 - ❖ De-identified information used/disclosed by NSU students to NSU faculty for exam purposes
 - ❖ Please see sample NSU “HIPAA Authorization for Use or Disclosure of Information Educational and Related Purposes”.
- 9.6 However, if a use or disclosure of PHI is for educational or treatment purposes, rather than research purposes, faculty, employees and students must refer and adhere to the relevant NSU Health Care Center/Clinic policies and procedures related to uses and disclosures. (See, for example, Policy 3C - uses and disclosures requiring authorization, Policy 4A – minimum necessary, Policy 7A – reasonable safeguards, Policy 7C – de-identification).

10. Transition Provisions for Existing Research

- 10.1 For patients who were enrolled in Research studies prior to April 14, 2003, the researcher may continue to use and disclose protected health information that was obtained in any of the following manners:
- With a signed authorization from the patient (even if the form was not HIPAA compliant) or other express legal permission for uses and disclosures related to the research study that was obtained prior to April 14, 2003.
 - With a signed informed consent for participation in the research study that was obtained prior to April 14, 2003.
 - With a waiver of informed consent from the IRB that was granted prior to April 14, 2003.

10.2 For existing studies approved prior to April 14, 2003 enrolling or reenrolling subjects and obtaining PHI, subjects are required to sign an Authorization Form.

Procedure:

1. Anyone conducting research at NSU, including anyone reviewing patient charts for an activity that could meet the definition of “research” as discussed in Section 9 of this Policy, must do one of the following:
 - a. Obtain a written authorization from each patient whose information will be used or disclosed (on NSU “Authorization for Research” form or form that complies with the requirements of Section 3 of this Policy)
 - b. Meet all of the requirements for a review preparatory to research, de-identified research, or a review of decedents’ information as set forth in Section 4 of this Policy.
 - c. Obtain a waiver of HIPAA authorization from the IRB board as set forth in Section 4 of this Policy.
2. For research performed outside of NSU, the researcher is responsible for complying with the research policies and procedures of the covered entity and for obtaining clearance from the Privacy Officer of that covered entity.
3. If a request for revocation is received by the researcher, he or she must immediately stop uses or disclosures of the patient’s information for the research study and alert the NSU Health Care Center’s Privacy Contact of the revocation if the research information is contained in the clinic chart.
4. Authorization forms must be kept by the researcher for a period of at least six (6) years with a copy to the clinic’s Privacy Contact if the research information is contained in the clinic’s patient record.
5. If the researcher does not obtain a written authorization because he or she meets one of the exceptions (reviews preparatory to research, review of a decedent’s patient information, or IRB waiver of authorization), he or she must complete the “Accounting of Disclosures for Research” Form.
6. Completed “Accounting of Disclosures for Research” Forms must be delivered to the Privacy Contact at the NSU Health Care Center where the research was conducted.
7. The Privacy Contact of the clinic will provide information to a patient who requests an accounting of disclosures in accordance with Section 6 of this policy. This information will be combined with other disclosures made pursuant to the clinic’s policy regarding uses and disclosures for special circumstances (Policy 3B).

Authorities:

- 45 CFR §164.501 (definition of research)
- 45 CFR §164.508 (authorization)
- 45 CFR §164.530 (documentation and retention)
- 45 CFR §164.512 (i) (research exceptions to authorization requirement)
- 45 CFR §164.528 (accounting of disclosures requirement)