



**Nova Southeastern University
Standard Operating Procedure for GCP**

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| Title: <u>HIPAA Research Policy: General</u> | | Version # 1 |
| SOP Number: OCR-HIP-001 | Effective Date: August 2013 | Page 1 of 5 |

PURPOSE: Federal privacy regulations implementing the Health Insurance Portability and Accountability Act (HIPAA) of 1996 went into effect April 14, 2003. The Privacy Rules set forth requirements for the use and disclosure of Protected Health Information (PHI) in research.

Nova Southeastern University, Inc. ("NSU") has implemented a series of policies with regard to HIPAA and research. These policies apply to: (1) all NSU covered health care clinics and departments that allow access to PHI by researchers for research; and (2) all researchers. Researchers must refer to these policies 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 Institutional Review Board ("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. 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. 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 at an outside entity. For additional guidance on research at outside entities See, HIPAA Research Policy No. 6.

POLICIES:

1. Definition of Protected Health Information (PHI):
 - 1.1 PHI is health information transmitted or maintained in any form or medium that:
 - 1.1.1 identifies or could identify an individual; and

- 1.1.2 is created or received by a healthcare provider, health plan, employer or healthcare clearinghouse; and
 - 1.1.3 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. The sources of PHI may include, but are not limited to, the following:
 - 2.1 PHI utilized for review preparatory to research to determine whether or not to begin a study (See, HIPAA Research Policy No. 4); and
 - 2.2 PHI stored in databases or repositories (e.g., a health care provider or hospital patient database); and
 - 2.3 PHI relating to living participants; and
 - 2.4 PHI relating to human tissue samples; and
 - 2.5 PHI relating to deceased persons.
3. Health-related information is not considered PHI if the researcher obtains it from:
 - 3.1 student records maintained by a school; or
 - 3.2 employee records maintained by an employer related to employment status; or
 - 3.3 information that has been de-identified in accordance with the regulations
4. General Rule Related to Research Uses and Disclosures:
 - 4.1. General Rule: HIPAA Authorization Required:

As a general rule, a HIPAA 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 authorization form.

*Please see the Nova Southeastern University Authorization for Use and Disclosure of Protected Health Information in Research attached as Exhibit 1.

*Please see the Instructions for Preparing the Authorization for Use and Disclosure of Protected Health Information in Research attached as Exhibit 2.

*Please see NSU HIPAA Notice of Privacy Practices attached as Exhibit 3 a. and Acknowledgment of Receipt of Notice of Privacy Practices attached as Exhibit 3 b.

*Please see Documentation of Good Faith Efforts Form attached as Exhibit 4.

The Nova Southeastern University Authorization for Use and Disclosure of Protected Health Information in Research must be kept in the patient's research chart and/or research section of the patient record for at least six (6) years. As noted in the instructions set forth in Exhibit 2, the patient must also be provided with a copy of the signed authorization form.

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:

- o 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.
- o With a signed informed consent for participation in the research study that was obtained prior to April 14, 2003.
- o With a waiver of informed consent from the IRB that was granted prior to April 14, 2003.

For existing studies approved prior to April 14, 2003 enrolling or reenrolling subjects and obtaining PHI, subjects are required to sign a Nova Southeastern University Authorization for Use and Disclosure of Protected Health Information in Research.

4.2. Revocation of Authorization:

- 4.2.1 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.
- 4.2.2 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.
- 4.2.3 It is also the researcher's responsibility to notify the clinic's Privacy Contact if the research information is contained in the clinic chart.

5 Education vs. Research Guidance:

- 5.1 The HIPAA Privacy Rule defines research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” There are some situations in which it is unclear as to whether certain activities are educational or fall within the category of “research.”
- 5.2 In order to provide further guidance in determining whether an activity constitutes “research”, the NSU IRB has created the attached information guide. Please see, the Attachment to the Nova Southeastern University Research Uses and Disclosures Policy and Procedure IRB Guidance on Research Versus Educational Activity, Exhibit 5. You may also contact the IRB with questions on this topic.
- 5.3 The scope of the NSU IRB’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.
- 5.4 The following are examples of some indicators that a project falls within the definition of research and requires IRB review:
 - 5.4.1 The activity is designed to test a hypothesis or permit conclusions to be drawn;
 - 5.4.2 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;
 - 5.4.3 The information is being gathered to create a data base or research repository for future research;
 - 5.4.4 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; and
 - 5.5.5 For a NSU researcher to participate in a research project at another site, the project needs to be reviewed by the NSU IRB as well as the other institution’s IRB.

6. Some examples of uses/disclosures that would be considered educational purposes and not research would include:
 - 6.1 Information used/disclosed for review of a student's performance;
 - 6.2 Information used/disclosed for classroom activities within NSU;
 - 6.3 Information used/disclosed for current or future teaching activities within NSU; and
 - 6.4 Information used/disclosed by NSU students to NSU faculty for exam purposes.

*For further examples please see the sample NSU HIPAA Authorization for Use or Disclosure of Information Educational and Related Purposes, attached as Exhibit

7. 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 HIPAA Privacy policies and procedures related to uses and disclosures. (See, for example, the applicable Health Care Center/Clinic HIPAA Privacy Policy 3C - uses and disclosures requiring authorization, Policy 4A – minimum necessary, Policy 7A – reasonable safeguards, Policy 7C – de-identification).
8. When HIPAA Authorization Is Not Required: 4 Key Exceptions
 - 8.1 As noted above, in most circumstances a HIPAA authorization is required for uses and disclosures related to research. However, HIPAA Authorization is not required in the following limited circumstances:
 - 8.1.1 IRB Waiver of HIPAA Authorization- See, HIPAA Research Policy No. 2
 - 8.1.2 De-identified information- See, HIPAA Research Policy No. 3
 - 8.1.3 Research on a Decedent's Information- See, HIPAA Research Policy No. 3
 - 8.1.4 Reviews Preparatory to Research- See, HIPAA Research Policy No. 4