Nova Southeastern University
Standard Operating Procedure for GCP

Title: HIPAA Research Policy No 2: IRB Waiver of HIPAA Authorization		Version # 1
SOP Number: OCR-HIP-002	**Effective Date: August 2013**	**Page 1 of 2**

PURPOSE: In most circumstances a HIPAA authorization is required for uses and disclosures related to research. However, a HIPAA authorization is not required if there is a documented waiver of authorization from the IRB. However, a NSU Accounting of Disclosures Form for Research , attached as Exhibit 7 will need to be completed for disclosures pursuant to an IRB waiver, in accordance with HIPAA Research Policy No. 5.

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.

POLICIES:

1. A researcher may request a waiver of authorization by going through the IRB. All waiver requests should be submitted through the standard IRB procedures. As part of this process, researchers must complete the IRB Waiver of Authorization Form attached as Exhibit 8.

   The IRB Board can grant a waiver of the authorization requirement if the following is documented and approved through full review of the IRB:

   1.1 A statement identifying the IRB and the date on which the waiver of authorization was approved.

   1.2 A statement that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals because:

   1.2.1 There is an adequate plan to protect the identifiable information from improper use and disclosure,

   1.2.2 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

1.2.3 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.

1.2.4 A statement that the research could not be conducted without the waiver.

1.2.5 A statement that the research could not be conducted without access to and use of the protected health information.

1.2.6 A brief description of the protected health information that is needed for the study.

1.2.7 A statement that the waiver has been reviewed by the IRB under full review procedures.

1.2.8 All alternative methods of conducting the study have been exhausted