



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

Title: <u>HIPAA Research Policy No 3: De-identified and Decedent Information</u>		Version # 1
SOP Number: OCR-HIP-003	Effective Date: August 2013	Page 1 of 3

PURPOSE: In most circumstances a HIPAA authorization is required for uses and disclosures related to research. However, a HIPAA authorization is not required if the information has been de-identified in accordance with the HIPAA regulations. HIPAA authorization is also not required for research if the patient is deceased, the use or disclosure is solely for research and is necessary to the research.

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. De-Identified Information Without Authorization:

- 1.1 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 a NSU Health Care Center/Clinic prior to the disclosure. As de-identifying data is considered part of health care operations, a NSU Health Care Center/Clinic is also permitted to provide PHI to a third party to perform this de-identification function pursuant to a Business Associate Agreement. Alternatively, a NSU Health Care Center/Clinic can provide PHI to a non-covered NSU component (i.e., a department that is not a covered component in the NSU hybrid entity designation) to perform the de-identification function.
- 1.2 In order for information to be considered de-identified, all of the following must be removed:
 - 1.2.1 Names

- 1.2.2 Geographic subdivisions smaller than a state (in certain circumstances, the first 3 digits of a zip code can be used)
 - 1.2.3 All elements of dates (except year) for dates directly related to an individual
 - 1.2.4 All ages or dates indicating an age over 89 (they can be lumped into one category of 90 or older)
 - 1.2.5 Telephone numbers
 - 1.2.6 Fax numbers
 - 1.2.7 Social security number
 - 1.2.8 Medical record numbers
 - 1.2.9 Health plan beneficiary numbers
 - 1.2.10 Account numbers
 - 1.2.11 Certificate/license numbers
 - 1.2.12 Vehicle identifiers and serial numbers
 - 1.2.13 Web universal resource locators (URLs)
 - 1.2.14 Internet Protocol (IP) address numbers
 - 1.2.15 Biometric identifiers, including finger and voice prints
 - 1.2.16 Full face photographic images and any comparable images
 - 1.2.17 Any other unique identifying number, characteristic or code
- 1.3 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.
 - 1.4 It is the policy of NSU that the de-identified research must be reviewed by the IRB prior to conducting the research.

2. Research on Decedent's Information Without Authorization

- 2.1 A HIPAA 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. As part of this process, researchers must complete the IRB Research on Decedent's Information Without Authorization form attached as Exhibit 9.
- 2.2 Note that a NSU Accounting of Disclosures Form for Research, attached as Exhibit 7 must be completed for these disclosures in accordance with HIPAA Research Policy No. 5.

- 2.3 Researchers may use and disclose the records of deceased patients for research purposes without obtaining authorization from a personal representative under the following circumstances:
 - 2.3.1 The use or disclosure sought is solely for research on the protected health information of the decedent;
 - 2.3.2 There is documentation of the death of the patients in question;
 - 2.3.3 The protected health information for which use or disclosure is sought is necessary for the research purposes; and
 - 2.3.4 The research is approved by the IRB.