Nova Southeastern University
Standard Operating Procedure for GCP

Title: HIPAA Research Policy No 4: Review Preparatory to Research		Version # 1
SOP Number: OCR-HIP-004	**Effective Date: August 2013**	**Page 1 of 9**

PURPOSE: Pursuant to 45 CFR Section 164.512 (i)(1)(ii) of the HIPAA Privacy Rules, a covered entity may use or disclose PHI for research in the context of reviews preparatory to research without patient authorization or IRB approval of a waiver of authorization only if the covered entity obtains from the researcher representations that:

1. The use or disclosure is sought solely to review PHI as necessary to prepare the research protocol or other similar preparatory purposes;
2. No PHI will be removed from the covered entity by the researcher in the course of review; and
3 The PHI that the researcher seeks to use or access is necessary for the research purposes.

Even though authorization is not required for review of these records, a NSU Accounting of Disclosures Form for Research, attached as Exhibit 7 will need to be completed for these records (See, HIPAA Research Policy 5).

This policy applies to:

(1) all NSU covered health care clinics and departments that allow access to PHI by researchers for reviews preparatory to research; and
(2) all researchers desiring to conduct reviews preparatory to research involving PHI maintained by a NSU clinic.

POLICIES:

1. General Internal Procedures:

Pursuant to the HIPAA regulations, reviews preparatory to research without patient authorization can be conducted by researchers who are part of the workforce of the particular covered NSU Health Care Center/Clinic that maintains the PHI and by researchers who are not part of the workforce of the

particular covered NSU Health Care Center/Clinic1 that maintains the PHI provided that all of the above-noted requirements are met. However, NSU has implemented the following internal procedures that must be complied with for reviews preparatory to research for each of the following categories:

1 NSU is a hybrid entity under the HIPAA regulations. Note that researchers who are not part of the workforce of the particular covered NSU Health Care Center/Clinic may include: (a) individuals who may be workforce members of another NSU Health Care Center/Clinic; (b) individuals who are workforce members of other NSU departments that may not be covered components (e.g., The NSU Office of Clinical Research); and (c) individuals who are not affiliated with NSU.

A. Researchers Within the Workforce of a Covered NSU Health Care Center/Clinic:

1.1 General:

Reviews preparatory to research involving PHI of a particular covered NSU Health Care Center/Clinic can be conducted by researchers who are part of the workforce of that particular Health Care Center/Clinic. In such cases, it is the internal procedure of NSU that such researchers are required to receive approval from the applicable NSU clinic and the IRB prior to commencement of any review preparatory to research. As part of this process, researchers must complete the IRB Review Preparatory to Research Form (Clinic Workforce Version) attached as Exhibit 10 which requires written certification by the researcher of the following:

1.1.1 The use or disclosure is sought solely to review PHI as necessary to prepare the research protocol or other similar preparatory purposes and will not be used in any research prior to IRB approval.

1.1.2 The PHI will not be removed from the health care facility.

1.1.3 The PHI is necessary for purposes of preparatory research.

1.2 Preparatory Activities and Recruitment Activities:

1.2.1 The HIPAA regulation governing preparatory research permits the covered NSU Health Care Center/Clinic to use or disclose PHI for purposes of "preparatory to research" only. This would permit researchers to undertake such activities as: "aid" in study recruitment; identify prospective research participants; chart reviews; and data base queries.

This particular HIPAA provision does not consider actual patient recruitment to be part of the permitted activities of reviews preparatory to research.

1.2.2 However, because 45 CFR 164.502(a)(1)(i) does allow a covered NSU Health Care Center/Clinic to disclose PHI of a patient directly to the patient, the Office of Civil Rights has taken the position that a researcher, who is a member of the workforce of the covered NSU Health Care Center/Clinic that maintains the PHI, may use the PHI to contact prospective research subjects. Therefore, researchers who are members of the workforce of the particular covered NSU Health Care Center/Clinic may contact the patient for recruitment purposes to discuss the option of enrolling in a clinical trial without patient authorization, and without an IRB waiver of the authorization.

1.2.3 Importantly, however, the researcher who is a member of the workforce cannot delegate recruitment (contacting the patients/prospective research subjects) to an assistant or any other individual who is not a member of the workforce of the covered NSU Health Care Center/Clinic.

B. Researchers Not Within the Workforce of a Particular Covered NSU Health Care Center/Clinic but Who Are Affiliated with another Covered NSU Health Care Center/Clinic:

2.1 General:

2.1.1 Reviews preparatory to research involving PHI of a particular covered NSU Health Care Center/Clinic can be conducted by NSU affiliated researchers who are not members of the workforce of that particular clinic. In such cases, it is the internal procedure of NSU that such researchers are required to receive approval from the applicable NSU clinic and the IRB prior to commencement of any review preparatory to research. As part of this process, researchers must complete the IRB Review Preparatory to Research Form (NSU Affiliate - Outside Researcher Version) attached as Exhibit 11 which requires written certification by the researcher of the following:

2.1.1.1 The use or disclosure is sought solely

to review PHI as necessary to prepare the research protocol or other similar preparatory purposes and will not be used in any research prior to IRB approval.

2.1.1.2 The PHI will not be removed from the health care facility.

2.1.1.3 The PHI is necessary for purposes of preparatory research.

2.2 Preparatory Activities and Recruitment Activities:

2.2.1 The HIPAA regulation governing preparatory research permits the covered NSU Health Care Center/Clinic to use or disclose PHI for purposes "preparatory to research" only. This would permit researchers to undertake such activities as: "aid" in study recruitment; identify prospective research participants; chart reviews; and data base queries. Patient recruitment is not part of the permitted activities of reviews preparatory to research.

2.2.2 Researchers, who are not members of the workforce of the particular covered NSU Health Care Center/Clinic that maintains the PHI, are not permitted to contact patients/prospective research subjects without a signed HIPAA authorization from the patient or without a waiver of the HIPAA authorization by the IRB. To clarify, researchers, assistants and staff that are not part of the particular covered NSU Health Care Center/Clinic's workforce including, but not limited to, individuals from the NSU Office of Clinical Research, cannot directly contact patients. These researchers are permitted to aid in recruitment including chart reviews and data base queries but cannot contact patients.

2.2.3 Importantly, any researcher who is part of the workforce of the particular covered NSU Health Care Center/Clinic that maintains the PHI cannot delegate patient recruitment to an assistant or any other individual who is not a member of the workforce of the covered NSU Health Care Center/Clinic.

C. Non-NSU Affiliated Researchers-"Outside Researchers 2"

3.1 General:

3.1.1 It is the internal policy of NSU that reviews preparatory to research involving PHI of a particular covered NSU Health Care Center/Clinic may only be conducted by outside researchers if the outside researchers receive approval from

the applicable covered NSU Health Care Center/Clinic and receive a specific waiver of patient authorization from the IRB3. As part of this process, outside researchers must complete the IRB Review Preparatory to Research Form (Non-NSU Researcher-Outside Researcher Version) attached as Exhibit 12 which requires written certification by the researcher of the following:

3.1.1.1 The use or disclosure is sought solely to review PHI as necessary to prepare the research protocol or other similar preparatory purposes and will not be used in any research prior to IRB approval.

3.1.1.2 The PHI will not be removed from the health care facility.

3.1.1.3 The PHI is necessary for purposes of preparatory research.

3.1.2 In addition, in order to be granted a waiver by the IRB, the outside researcher must provide specific reasons for seeking the waiver, including, but not limited to, why the preparatory research could not be practicably done with de-identified information or with patient authorization.

3.2 Preparatory Activities and Recruitment Activities:

3.2.1 If the IRB grants the waiver of authorization permitting the outside researcher to conduct the review preparatory to research, the outside researcher may only conduct limited activities with the information. This activity could include activities to, "aid" study recruitment; identify prospective research participants; chart reviews; and data base queries. The outside researcher is prohibited from contacting patients/prospective research subjects or otherwise engaging in any activity to recruit patients.

2. Restriction on Removal of PHI:

2.1 With regard to reviews preparatory to research, no PHI may be removed by the researcher from the particular covered NSU Health Care Center/Clinic that maintains the PHI in the course of review. All researchers are required to certify in writing as part of the IRB approval process that they will not remove any PHI from the premises of the covered NSU Health Care Center/Clinic in conducting reviews preparatory to research.

2 Note that the term outside researchers is used in this section to describe individuals who are not affiliated with any NSU clinic or department.

3 Although the HIPAA regulations do permit a covered entity to allow outside researchers to engage in reviews preparatory to research without patient authorization or without a waiver of authorization granted from the IRB, NSU has implemented an internal policy requiring an IRB waiver of authorization specific to reviews preparatory to research by outside researchers.

2.3 It is the policy of NSU that researchers are not permitted to remotely/electronically access PHI at the particular covered NSU Health Care Center/Clinic and they are not permitted to remove any patient identifying information from the premises of the clinic including but not limited to: (a) patient names; (b) patient charts; and (c) any other report, list or document that contains information pertaining to a patient. This prohibition on removal of PHI from the premises applies to all forms of PHI including hardcopy and electronic medium.

2.4 All covered NSU Health Care Center/Clinic permitting researchers to access PHI for reviews preparatory to research must oversee that the researchers are complying with this requirement.

3. Records With Special Protection:

3.1 Notwithstanding anything to the contrary above, if the review preparatory to research involves: (1) alcohol or substance abuse records governed by 42 CFR Part 2; (2) HIV records subject to Florida Statutes Section 381.004; or (3) mental health records subject to Section 394.4615 of the Florida Public Health Code, special rules will apply and must be complied with as described below.

Notwithstanding anything to the contrary above, if the review preparatory to research involves: (1) alcohol or substance abuse records governed by 42 CFR Part 2; (2) HIV records subject to Florida Statutes Section 381.004; or (3) mental health records subject to Section 394.4615 of the Florida Public Health Code, special rules will apply and must be complied with as described below.

A. Alcohol or Substance Abuse Records governed by 42 CFR Part 2:

3.1.2 Overview:

3.1.3 Absent specific written consent from the patient:

3.1.4 PHI may only be disclosed in the context of conducting scientific research if the program director makes a determination that the recipient of the patient identifying information:

3.1.4.1 Is qualified to conduct the research;

3.1.4.2 Has a research protocol under which the patient identifying information (i) will be maintained in accordance with the security protocols under the regulations; and (ii) will not be re-disclosed except as permitted under the regulations; and

3.1.4.3 Has provided a satisfactory written statement that a group of 3 or more who are independent of the research project has reviewed the protocol and determined that the rights of the patients will be adequately protected and the risks in disclosing the patient identifying information are outweighed by the potential benefits of the research.

3.1.5 A person conducting research may disclose patient identifying information obtained under paragraph (a) of this section only back to the program from which that information was obtained and may not identify any individual patient in any report of that research or otherwise disclose patient identifiers.

3.2.1 Procedure:

3.2.1.1 Any researcher desiring to access PHI for reviews preparatory to research involving records protected under 42 CFR Part 2, must receive approval from the applicable covered NSU Health Care Center/Clinic and the IRB prior to commencement of the review preparatory to research. As part of this process, in addition to completing the appropriate form (IRB Review Preparatory to Research Form (Clinic Workforce Version) attached as Exhibit 10; IRB Review Preparatory to Research Form (NSU Affiliate - Outside Researcher Version) attached as Exhibit 11; or IRB Review Preparatory to Research Form (Non-NSU Researcher-Outside Researcher Version) attached as Exhibit 12) researchers must also complete the 42 CFR Part 2 Addendum attached as Exhibit 13.

B. HIV Records:

3.3.1 Overview

3.3.1.1 HIV records have special protections under Florida law. Pursuant to Section 381.004 of the Florida Statutes, HIV test results are confidential and cannot be disclosed except in certain circumstances. The statute does provide that disclosures which allow identification of the test subject are permitted to:

Authorized medical or epidemiological researchers who may not further disclose any identifying character

3.4.1 Procedure:

3.4.1.1 Any researcher desiring to access PHI for reviews preparatory to research involving records protected under 42 CFR Part 2, must receive approval from the applicable covered NSU Health Care Center/Clinic and the IRB prior to commencement of the review preparatory to research. As part of this process, in addition to completing the appropriate form (IRB Review Preparatory to Research Form (Clinic Workforce Version) attached as Exhibit 10; IRB Review Preparatory to Research Form (NSU Affiliate - Outside Researcher Version) attached as Exhibit 11; or IRB Review Preparatory to Research Form (Non-NSU Researcher-Outside Researcher Version) attached as Exhibit 12) researchers must also complete the 42 CFR Part 2 Addendum attached as Exhibit 14.

C. Mental Health Records: Section 394.4615 of the Florida Public Health Code and Rule 65E-5.250

3.5.1 Overview

3.5.1.1 Mental health records are subject to special protections and absent certain exceptions cannot be released without authorization. According to the Florida Public Health Code Section 394.4615 3(b), information can be released:
When the administrator of the facility deems release to a "qualified researcher" is necessary for compilation of treatment data or evaluation of programs.

3.5.1.2 A qualified researcher is one who after making an application to review confidential data and who, after

documenting his or her bona fide academic, scientific or medical credentials and describing the research that gives rise to the request, is determined by the administrator to be eligible to review the data. Notably, personal identifying information obtained by such researcher shall not be further disclosed without the expressed and informed consent of the individual who is the subject of the information.

Information may also be released for statistical and research purposes if the information is abstracted in such a way as to protect the identity of individuals

3.6 Procedure:

3.6.1 Any researcher desiring to access PHI for reviews preparatory to research involving mental health records protected under the Florida Public Health code must receive approval from the applicable NSU clinic and the IRB prior to commencement of the review preparatory to research. As part of this process, in addition to completing the appropriate form (IRB Review Preparatory to Research Form (Clinic Workforce Version) attached as Exhibit 10; IRB Review Preparatory to Research Form (NSU Affiliate - Outside Researcher Version) attached as Exhibit 11; or IRB Review Preparatory to Research Form (Non-NSU Researcher-Outside Researcher Version) attached as Exhibit 12) researchers must also complete the Mental Health Records Addendum attached as Exhibit 15.