



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

Title: <u>Recruiting Patients within NSU Health Care Centers/Clinics and Therapeutic Relationship</u>		Version # 1
SOP Number: OCR-RR-004	Effective Date: August 2013	Page 1 of 9

PURPOSE: People, in general, have the right to know of active research needing volunteers as well as a right to privacy. Overzealous researchers may infringe on privacy rights and overprotective privacy practices may infringe upon the right of knowledge on active research, particularly research that may have a direct or indirect benefit to the person. Maximizing one right without infringing upon another is part of the challenge researchers and society face today.

POLICIES:

1. The NSU HIPAA Research Uses and Disclosures Policies and Procedures must be followed when recruiting potential subjects from existing NSU Health Care Center/Clinic's patient database.
2. Approval must be obtained prior to reviewing patient charts or databases from the NSU Health Care Center/Clinic and IRB.
3. When querying patient's records (paper or electronic), databases, other forms of PHI NSU a **NSU Accounting of Disclosure for Research Form** must be completed and filed in each chart reviewed.
4. Adherence to NSU HIPAA Research Policy # 4: Review Preparatory to Research.

http://www.nova.edu/irb/manual/forms/hipaa_preparatory_reviews.pdf

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. Researchers who are not part of the workforce of the particular covered NSU Health Care Center/Clinic that maintains the PHI may review preparatory to research provided that all of the above-noted requirements are met. NSU has implemented the following internal procedures that must be complied with for reviews preparatory to research for each of the following categories:

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) 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:

1.1 General:

1.1.1 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) which

requires written certification by the researcher of the following:

- 1.1.1.1 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.
- 1.1.1.2 The PHI will not be removed from the health care facility.
- 1.1.1.3 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 "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.
- 1.2.2 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.
- 1.2.3 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"

1.1 General:

1.1.1 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) which requires written certification by the researcher of the following:

1.1.1.1 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.

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

1.1.1.3 The PHI is necessary for purposes of preparatory research.

2.1 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.

3.1 Preparatory Activities and Recruitment Activities:

3.1.1 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.

2.2 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.

2.3 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.

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); IRB Review Preparatory to Research Form (NSU Affiliate - Outside Researcher Version); or IRB Review Preparatory to Research Form (Non-NSU Researcher-Outside Researcher Version) researchers must also complete the 42 CFR Part 2 Addendum

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); IRB Review Preparatory to Research Form (NSU Affiliate - Outside Researcher Version); or IRB Review Preparatory to Research Form (Non-NSU Researcher-Outside Researcher Version) researchers must also complete the 42 CFR Part 2 Addendum

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); IRB Review Preparatory to Research Form (NSU Affiliate - Outside Researcher Version); or IRB Review Preparatory to Research Form (Non-NSU Researcher-Outside Researcher Version) researchers must also complete the Mental Health Records Addendum.

4 Database Query and Chart Review:

1. Once approval is received for Review Preparatory to Research a request may be submitted to Clinical Information Support at cissupport@nova.edu to run a database query of existing patients in the NSU Health Care Center/Clinic that may qualify for the study. Provide Clinical Information Support with a diagnostic code (ICD-9 code) and other criteria that may narrow the search.
2. The database query will provide the names of patients whose chart may be reviewed to determine eligibility for the research.
3. A NSU Accounting of Disclosure for Research Form must be completed for each patient's chart reviewed and filed in that chart.

5. Respecting Subject Therapeutic Relationships in Recruitment

1. Although people have the right to self-determination, respect for current providers and their existing therapeutic relationships should be considered in their decision.
2. For subjects seeing other providers, the subject should return to their original provider upon their completion of or withdrawal from the protocol.
3. When recruiting existing patients of principal investigator, considerations of therapeutic misconception must be addressed.
 - 3.1. The investigator must inform potential subject there may be no therapeutic benefit from participating in the research.
 - 3.2. The investigator must inform the potential subject that they are not obligated to participate in the research and their refusal to do so will not impact their care at NSU Health Care Centers/Clinics now or in the future.