UNIVERSITY OF NORTH CAROLINA AT GREENSBORO

INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS

Application to Use PHI in Research

**BACKGROUND:** The HIPAA Privacy Rule governs disclosure of personally identifiable health information (deemed “protected health information”-PHI) by hospitals, physicians, and other HIPAA-defined “Covered Entities” (CEs). NOTE: PHI is broadly defined by HIPAA to include identifiable data on a person’s physical or mental health, health care, or payment for health care. For example, a list of a person’s current medications is PHI. So is a person’s weight, smoking status, or date of surgery.

HIPAA defines “Covered Entities” as hospitals, physicians, health care providers, insurance agencies, or others who maintain or transmit PHI for purposes of treatment, payment, or health care operations (such as accreditation programs). Most researchers are not themselves CEs, because they do not maintain or transmit health data for purposes of treatment, payment, or health care operations. However, many researchers obtain PHI from CEs as part of their research projects. The HIPAA Privacy Rule governs the circumstances under which CEs can disclose PHI to researchers.

NOTE: Health data that a researcher obtains directly from research participants, rather than from CEs, is NOT subject to the HIPAA Privacy Rule. For example, if a researcher takes a subject’s blood pressure, that data is not subject to the Privacy Rule. If, on the other hand, the researcher wants to obtain the subject’s blood pressure from a physician, the physician’s ability to disclose the information is governed by the Privacy Rule. Similarly, a physician sending a “medical clearance” form for a study participant to a researcher would be subject to HIPAA. However, if the physician gave the medical clearance form to the study participant, and the study participant delivered it to the researcher, the disclosure would NOT be subject to HIPAA.

The Privacy Rule permits, under section 164.512(i)(1)(ii), a covered entity to provide investigators with access to PHI for purposes preparatory to research, such as identifying potential human subjects to aid in study recruitment. Such access is permitted provided that the covered entity receives certain required representations from the researcher and the researcher does not remove any PHI from the covered entity during the course of the review.

There are 3 conditions under which a CE can release PHI to a researcher:

1. Every subject has signed an authorization for the CE to release the PHI to the researcher.
2. An IRB has granted the researcher a waiver of authorization.
3. The researcher de-identifies the health information to HIPAA standards.

Each of these 3 conditions will be discussed briefly. More detailed information on each follows on subsequent pages. Please read all the information before deciding which approach to use in your study.

**Authorization:** In most research cases, each subject must sign an authorization for the CE to release PHI to the researcher. Authorizations are separate from consent forms, and must contain specific information. Hospitals and other large CEs may require the researcher to use their standard agency authorization form. Researchers are advised to contact CEs and determine this before investing time in creating an authorization form specific to their research study. The information that must be in an authorization is listed on page 3 of this packet. Sample authorization forms can be obtained from ORC.

**Waiver of Authorization:** An IRB can grant a waiver of authorization for release of PHI for a research study if it determines that obtaining a signed authorization from each subject is impractical, and that the researcher has taken sufficient safeguards to protect the data. A Request for Waiver of Authorization form is attached. However, researchers should be aware that CEs with their own IRBs might require that the waiver be granted by the agency IRB, rather than UNCG’s IRB. Researchers are advised to contact CEs and determine this before applying for a Waiver of Authorization from the UNCG IRB.

**De-identification and Limited Data Sets:** De-identification to HIPAA standards requires removing considerable information, in addition to names. A list of data elements that must be removed is shown on page 5.

**Note:** The burden for complying with HIPAA falls on the CE, so it is ultimately the responsibility of the CE to determine if the conditions that allow disclosure of PHI have been met. The UNCG IRB can help researchers throughout the process, but the CE will always be the one to make the final decision about whether PHI can be shared with a researcher.

Application to Use PHI in Research

 Complete this application and attach it to your IRB application.

1. Name the Covered Entity or Entities from whom you wish to obtain PHI in this study, and briefly describe the PHI you wish to obtain.

Covered Entities: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. Indicate below all applicable plans to obtain PHI and the type of PHI to which each applies.

A. Will each subject sign an Authorization to Release the PHI?

\_\_\_ No

\_\_\_ Yes PHI to be obtained: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If yes, will they sign a:

 \_\_\_\_\_ standard authorization form provided by the Covered Entity, or

\_\_\_\_\_ form the researcher has designed for this study. If you are NOT using a standard form provided by the Covered Entity, attach a copy of the form you will use.

B. Are you requesting a Waiver of Authorization for this study?

\_\_\_ No

\_\_\_ Yes PHI to be obtained: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If yes, are you requesting the Waiver of Authorization from

 \_\_\_\_\_ the Covered Entity’s IRB, or

\_\_\_\_\_ UNCG’s IRB. If you are requesting the Waiver from UNCG’s IRB, complete and attach the **UNCG Request for Waiver of Authorization** (from page 4 of this packet.)

C. Do you plan to de-identify the health information to HIPAA standards?

\_\_\_ No

\_\_\_ Yes PHI to be obtained: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If yes, briefly describe the process you will use to de-identify data:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note: the CE (NOT the UNCG IRB) must make the determination that the plan for de-identification is adequate.

**Additional Information:**

**AUTHORIZATIONS**

**Authorization:** In most research cases, each subject must sign an authorization for the CE to release PHI to the researcher. Authorizations are separate from consent forms, and must contain the specific information listed below. Hospitals and other large CEs may require the researcher to use their standard authorization form. Researchers are advised to contact CEs and determine this before investing time in creating an authorization form specific to their research study. Sample authorization forms can be obtained from ORC or your IRB representative. An authorization must be written in plain language and include the following elements (45 CFR 164.508):

# An AUTHORIZATION must contain:

1. Description of information to be disclosed

2. Specifications of persons or class of persons authorized to disclose the information

3. Specifications of who (name or class of persons) that disclosure can be made to

4. Purpose for which disclosed data would be used

5. Expiration date for authorization

6. Statement of right to revoke authorization and method to revoke

7. Statement that person can inspect or copy PHI to be disclosed

8. Whether PHI disclosure is linked to remuneration or benefit for CE

9. Statement that disclosed information may be re-disclosed and will no longer be protected by HIPAA

10. Signed and dated by individual/guardian. If guardian signs, description of guardian’s authority to act for individual.

SAMPLE AUTHORIZATION TO DISCLOSE PHI- Specific to a Research Study

*Dr. Ella Savant and Dr. Sara Sagacious from the University of North Carolina at Greensboro* are conducting a research study on breast-feeding success. They have requested permission to contact women who have recently given birth at Eli Whitney Regional Hospital, to see if the women are willing to participate in their study.

By signing below, you are authorizing *Eli Whitney* *Regional Hospital*  to release *your name, phone number, type of delivery, and delivery date* to *Dr. Savant and Sagacious* for contact about participating in their research study. This authorization will expire in 1 year, unless you revoke it in writing before that date. If you wish to revoke the authorization, contact *Dudley Doright, IRB Chair, Eli Whitney Regional Hospital*  *(336 929- 4901.)* A revocation will not apply to any personal health information that was released under this authorization before the date of revocation.

If you choose NOT to authorize release of this information, it will not affect your health care at Eli Whitney Regional Hospital. Eli Whitney Regional Hospital will not receive money or other benefit from releasing this information on you. You have a right to inspect or copy the information to be disclosed. You have a right to a copy of this authorization.

If you allow release of this information to Dr. Savant and Dr. Sagacious, the information will no longer be subject to the Health Information Portability and Accountability Act (HIPAA). Dr. Savant and Dr. Sagacious may disclose it without contacting you again for further authorization.

I authorize \_*Eli Whitney Regional Hospital Medical Records*\_to release the following information to \_ *Dr. Ella Savant and Dr. Sara Sagacious* \_: *name, phone number, type of delivery, and delivery date*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signed \_\_\_\_\_\_\_\_\_\_\_Date

Patient is unable to signed because s/he is \_\_\_ years old or \_\_\_\_\_\_\_\_ (reason)

Guardian/Parent (circle) signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Additional Information:**

**WAIVER OF AUTHORIZATION FOR RELEASE OF PHI**

**Waiver of Authorization\*:** An IRB can grant waiver of authorization for a research study if it determines that (45 C.F.R. 164.512(i)):

(A) The use or disclosure of protected health information (PHI) involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

 (1) An adequate plan to protect the identifiers from improper use and disclosure;

 (2) An adequate plan to destroy the 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

 (3) Adequate written assurances that the PHI 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 PHI would be permitted by this HIPAA and approved by the IRB;

 (B) The research could not practicably be conducted without the waiver or alteration; and

 (C) The research could not practicably be conducted without access to and use of the PHI.

CEs with their own IRBs may require that the waiver be granted by the agency IRB, rather than UNCG’s IRB . Researchers are advised to contact CEs and determine this before applying for a Waiver of Authorization from the UNCG IRB. If you wish to request a Waiver of Authorization from the UNCG IRB, complete the Request for Waiver of Authorization, below.

\*additional rules apply to research on deceased people, and disclosures to PREPARE research protocols. Contact ORC for these rules.

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# UNCG Request for Waiver of Authorization

RESPOND TO ITEMS 1-6 BELOW, ON SEPARATE PAPER. Sign and attach the certification at the bottom.

1. What health information will to be obtained from the Covered Entity? (List the specific data elements, such as age, weight, data of surgery, date of admission to hospital, medications given during surgery).
2. Describe why the research could not practicably be conducted without access to and use of the health information. Why do you need this information for your study?
3. Describe why the research could not practicably be conducted without a waiver of authorization. Why is it not practical to have each subject sign an authorization for the CE to disclose the data to the researcher?
4. How and from whom will the data be obtained? (e.g., Will the researcher review the subjects’ medical records to extract the data? Will a physician’s office provide a list? Will the hospital provide a data set?)
5. What is your plan to protect the data from improper use and disclosure?
6. When and how will identifiers in the data be destroyed?

I certify that the protected health information obtained in this study 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 HIPAA and approved by the IRB.

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Date

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Student Researcher Date

**Additional Information:**

**DE-IDENTIFICATION AND LIMITED DATA SETS**

**De-identification:** Health information that cannot be traced to an individual is not subject to the HIPAA Privacy Rule (45 CFR 164.514). The Covered Entity (NOT the UNCG IRB) must make this determination. The determination can be made through either 1) expert opinion, or 2) removal of identifying information.

1. Expert opinion must be rendered by a person with expertise in methodology for de-identifying PHl. The expert must determine that risk of identification is very small and must document his/her methodology and analysis.

2. Removal of identifiers: The CE must NOT have actual knowledge that the disclosed information could be used to identify the subject. Must remove all identifiers of subjects, and their relatives, employers, and household members.

HIPAA REQUIRES REMOVAL OF:

Names

Addresses

Geographic subdivisions smaller than state

All dates related to the subject (e.g. birth date) [Exception: Birth year and age (if under 89) may be retained.]

Telephone, fax, e-mail, SSNs

Medical record and health plan numbers

Account numbers

Certificate and license numbers

VIN and license plate numbers

Device identifiers and serial numbers

URLS and IP addresses

Fingerprints, voice prints, etc

Images

Any other identifiers

Since the Covered Entity must make the determination that data have been sufficiently de-identified, the role of the UNCG IRB is education and advice. The IRB can assist researchers in deciding which data must be removed in order for the data to be considered de-identified.

HIPAA also allows a researcher and a Covered Entity to develop a Data Use Agreement will allows use of a Limited Data Set (see 45 CFR 164.514e). The Limited Data Set still must exclude identifiers such as name, address, and ID numbers; but may include some information not permitted in a de-identified data set. The Covered Entity must determine that the Data Use Agreement and the Limited Data Set meet HIPAA standards.

**Institutional Review Board**

**Guidance for HIPAA Security Standards**

Covered Entities (CE) must assure their customers (for example, patients, insured individuals, providers, and health plans) that the integrity, confidentiality, and availability of electronic protected health information they collect, maintain, use, or transmit is protected. The confidentiality of protected health information (PHI) is threatened by the risk of interception during electronic transmission of the information. The current guidance is designed to adopt national standards and safeguards to protect the confidentiality, integrity, and availability of electronic protected health information.

The HIPAA security regulations states that covered entities that maintain or transmit health information are required to maintain reasonable and appropriate administrative, physical, and technical safeguards to ensure the integrity and confidentiality of the information and to protect against any reasonably anticipated threats or hazards to the security or integrity of the information and unauthorized use or disclosure of the information. These safeguards must also otherwise ensure compliance with the statute by the officers and employees of the covered entities.

When researchers from UNCG obtain PHI electronically from covered entities, they are responsible for adhering to the policies and procedure of the covered entity where the information was obtained. The university has several policies to supplement requirement of the covered entity and aid in ensuring compliance. The [HIPPAA Compliance Policy](http://www.uncg.edu/apl/POLICIES/hipaa.htm) elaborates on the university’s position on HIPAA and gives valuable information about Business Associates (BA). PHI that researchers have stored electronically should be classified as “Restricted” and safeguarding this information should follow guidelines as articulated in the [Data Classification Policy](http://www.uncg.edu/apl/POLICIES/data_class.htm). PHI that is transmitted via E-Mail is not subject to becoming a public record as defined by NC state regulations. However researchers are advised to adhere to the [E-Mail Retention Policy](http://www.uncg.edu/apl/POLICIES/iip019.htm) which will provide information on the proper safeguards for the use of E-Mail messages. Specific security standards are currently under development which will provide even further guidance in regards to the HIPAA security standards. The university’s HIPAA’s Compliance Security Officer is available to provide further assistance with the above mentioned polices and other related concerns researchers may have in regards to HIPAA security.