CAPE FEAR VALLEY HEALTH	**IRB Guidance:** HIPPA & Human Subjects Research

When research will involve the use of Protected Health Information (PHI), criteria under the Health Insurance Portability and Accountability Act (HIPAA) may apply and the researcher will need to address how their research meets HIPAA requirements in the research submission.

HIPAA Covered Entities

Researchers working at or obtaining data from HIPAA covered component of CFVHS will have to comply with HIPAA use and disclosure requirements if their research involves protected health information. Please see additional CFVHS policies regarding the use and disclosure of HIPAA covered information.

Protected Health Information

Protected Health Information (PHI) includes any individually identifiable health information transmitted or maintained in any form or medium (e.g., electronic, paper, oral) by a covered entity or its business associate.

Individually identifiable health information is information, including demographic data, that relates to:

- The individual's past, present or future physical or mental health or condition,
- The provision of health care to the individual, or
- The past, present, or future payment for the provision of health care to the individual, and
    - That identifies the individual, or
    - For which there is a reasonable basis to believe it can be used to identify the individual.

List of Protected Health Information (PHI) Identifiers

1. Names.
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census:
    a. The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people.
    b. The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers.
5. Facsimile numbers.
6. Electronic mail addresses.
7. Social security numbers.
8. Medical record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.
11. Certificate/license numbers.
12. Vehicle identifiers and serial numbers, including license plate numbers.

13. Device identifiers and serial numbers.
14. Web universal resource locators (URLs).
15. Internet protocol (IP) address numbers.
16. Biometric identifiers, including fingerprints and voiceprints.
17. Full-face photographic images and any comparable images.
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

De-Identified Health Information

Researchers should note that are no restrictions under HIPAA for the use or disclosure of *de-identified* health information. De-identified health information neither identifies nor provides a reasonable basis to identify an individual.

HIPAA provides only two ways to de-identify information, either:

1. ***Expert Determination:*** A formal determination by a qualified statistician; or
2. ***Safe Harbor:*** The removal of 18 specified identifiers of the individual and of the individual's relatives, household members, and employers is required, and is adequate only if the covered entity has no actual knowledge that the remaining information could be used to identify the individual.

Researcher who require access to individually identifiable health information must either have each participant whose PHI is being gathered sign a HIPAA Authorization form (the CFVHS IRB approved informed consent has HIPAA authorization language included) or request that the IRB/HIPAA Privacy Board waive the authorization requirement.

HIPAA Authorization

Researcher requesting HIPAA Authorization can either include language in their regular informed consent form or can include a separate authorization form during the consent process. The HIPAA Authorization must be written in plain language and include six core elements and three required statements. CFVHS IRB consent templates and HIPAA Authorization template contain the required language.

Authorization Core Elements:

- A specific and meaningful description of the PHI to be used.
- The name(s) or specific identification of the person(s) or class of person(s) who will make the disclosure.
- The name(s) or specific identification of the person(s) who will use the PHI or to whom the covered entity will make the disclosure.
- Description of each specific purpose of the requested disclosure. Once researcher have obtained PHI, it may not be used for any purposes except those describe in the Authorization. ***Authorizations are project-specific and may not be used for future unspecified research.***
- Authorizations expiration date. Researcher may use the terms "end of the research project" or "none" if the PHI is collected for research.
- The individual's signature and the date the Authorization is signed.

Authorization Required Statements

- A statement of the individual's right to revoke the Authorization at any time in writing and a description of how to revoke the Authorization.

- A notice of the covered entity's ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the Authorization, including research-related treatment, and, if applicable, the consequences of refusal to sign the Authorization.

  NOTE: In most research at CFVHS, this statement should simply indicate that refusing to sign the Authorization will not affect the subject's medical care and will result only in the subject being excluded from the research.

- A statement explaining that the investigator receiving the data could potentially re-disclose the PHI and that the HIPAA Privacy Rule does not apply to the re-disclosure.

The IRB has developed a ***CFVHS Authorization Template*** for researchers to use when not using an IRB informed consent template.

HIPAA Waiver

Investigators requesting either a partial or total waiver of HIPAA Authorization must demonstrate that their research meets the following requirements listed below. The ***IRB Attachment – A: HIPAA – Use of PHI*** must be used when requesting a waiver of HIPAA Authorization.

A HIPAA waiver is appropriate where the **all** following criteria are met;

- The use or disclosure involves no more than a minimal risk to the privacy of individuals:
  - An adequate plan presented to the IRB or Privacy Board to protect PHI identifiers from improper use and disclosure;
  - An adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is otherwise required by law; and
  - Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research project, or (c) for other research for which the use of discourse of the PHI is permitted by the Privacy Rule;
- The research could not practicably be conducted without the requested waiver or alteration; and
- The research could not practicably be conducted without access to and use of the PHI.

Finally, HIPAA provides for several exceptions to the Authorization/Waiver requirement for the use of protected health information, including activities "preparatory to research," research solely on decedents, "limited data sets," and where research permission are allowable by the transition provisions of the Privacy Rule. Please note that specific criteria are needed to be met under HIPAA for these exceptions to apply.

For more information please contact the IRB Office.