What is HIPAA?

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule established a category of health information; Protected Health Information (PHI). PHI may only be used or disclosed by a covered entity under certain circumstances. Investigators wishing to utilize health information must ascertain whether data they wish to collect falls within the HIPAA Privacy Rule. More information can be found in the federal regulations at 45 CFR 160 and 45 CFR 164.

PNWU is not a covered entity, therefore the majority of research conducted at PNWU will not be covered by the HIPAA Privacy Rule.

The investigator will need to include a HIPAA Authorization in the IRB application if:

a. the investigator intends to utilize a covered entity to recruit subjects;
b. the investigator intends to collect PHI maintained by a covered entity as a data set in the research;
c. the investigator is a covered entity (a health care provider) and is including subjects in a research protocol due to medical diagnosis and is utilizing PHI from a covered entity.
d. The investigator is a covered entity (health care provider) and is incorporating health care interventions for the purpose of treatment in the research protocol, and will be maintaining and transmitting PHI to a medical record set as a result of this intervention.

What is Protected Health Information (PHI)?

Protected health information (PHI) includes all individually identifiable health information collected, transmitted or maintained by a covered entity. PHI may be electronic, paper or oral and includes information on:

- past, present or future physical or mental conditions;
- past, present or future provision of care to individuals;
- or past, present or future payment for provision of health care to individuals.

PHI includes living individuals and individuals who are deceased. PHI does not include information that has been de-identified.

Rights of research participants under HIPAA:

Under HIPAA research participants have the right to:

- privacy of protected health information;
- authorize use of identifiable PHI for research purposes;
- an accounting of how identifiable PHI was disclosed for research without authorization;
• revoke authorization in writing. No further PHI may be collected for the research after the authorization is revoked. (Researchers may continue to use and disclose PHI that was obtained under the authorization to maintain the integrity of the research.)

**Identified and de-identified health information:**

Individually identifiable means that the information identifies the individual or may identify the individual. There are 18 items under the federal privacy rule that are considered to be identifiers. They include:

1. Names
2. Medical Record Numbers
3. Geographic subdivisions smaller than a state (street address, city, county, zip code)
4. All elements of dates — date of birth, date of death, date of services (e.g., transplant or surgery date), admission and discharge dates, and all ages over 89
5. Telephone numbers
6. Fax numbers
7. Email addresses
8. Social Security Numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate and license numbers (including driver’s license)
12. Vehicle identifiers and serial numbers (including license plate numbers)
13. Device identifiers and serial numbers
14. Web Universal Resource Locator (URL)
15. Biometric identifiers, including finger or voice prints.
16. Full face photographic images or comparable images
17. Internet Protocol Address numbers
18. Any other unique identifying number, characteristic, or code (including unique study codes).

De-identified health information is health care information that does not contain any of the identifiers listed above. When reviewing research that will use de-identified health information, the IRB will need to review all of the data fields that will be utilized in the research project to be assured that the PHI collected could not be used to identify the study participants. *(A copy of the data collection tool should be submitted with the IRB application.)*
Tracking Release of PHI under HIPAA:

Patients have the right to obtain an accounting of how their PHI was disclosed without their authorization. Covered entities are required to track disclosures of PHI that were done without authorization. Covered entities must keep disclosure records for six years (after the last disclosure). The information that must be tracked includes:

1. Participant name
2. Date of the disclosure
3. The name and address of the investigator who received the PHI
4. A brief description of the PHI that was disclosed
5. A brief description of the purpose the PHI was disclosed (a reasonable explanation of why the PHI was disclosed).

*NOTE: No accounting is required for PHI disclosed with an authorization, limited data sets or de-identified PHI.*

Waiver of HIPAA Authorization:

Under the federal regulations there are specific criteria that must be met for the IRB to approve a waiver of HIPAA Authorization. There are additional requirements for HIPAA that are more stringent than for a waiver under the Common Rule. To apply for a waiver of authorization to use PHI in research, the research must meet all of the following criteria:

a. The use or disclosure of PHI will involve no more than minimal risk to the privacy of the individual.
b. The research could not be practicably conducted without the waiver.
c. The research could not be practicably conducted without the PHI.

The IRB application and/or research protocol must:

1. indicate how PHI will be used or created in the research (e.g., participant interview or questionnaires will be utilized to collect the date, existing medical records will be used to determine if the individual is eligible to participate in the study).
2. justify what identifiable information is needed (*minimum necessary,*
3. specify how the PHI will be protected from improper use or disclosure,
4. specify when the identifiers will be destroyed (*earliest opportunity,* and
5. have a written assurance that the PHI will not be used or disclosed to a third party except as required by law.

*Note: All research projects granted a waiver of HIPAA Authorization by the IRB, must track release of PHI. Some covered entities may require you to submit disclosure tracking information to their medical records department.*
Limited Data Sets and Data Use Agreements:

A limited data set contains a limited number of identifiers from the list of 18 identifiers stated earlier in this document. A limited data set allows the researcher to use and disclose PHI contained in the limited data set. A limited data set may include:

1. Date of birth; date of death
2. Dates of admission, discharge or service
3. Age
4. Geographical information such as state, county, city, precinct or 5 digit zip code

Investigators are typically required to sign a data use agreement with the covered entity. The data use agreement will specify:

1. the permitted use, restrictions, and disclosure of the data,
2. who may use or receive the data set,
3. the restrictions for re-identification of data or for contact with the individuals.