

**Please acknowledge that you have read, understood, and accepted this content by signing the bottom of this form.** Complete this form in its entirety and submit through IRBNet: along with supporting documentation required per HRPP Policy.

Whether frequently or infrequently, many investigators will use, disclose, or access Protected Health Information (PHI) for research purposes. In some research projects, PHI is recorded in order to organize and analyze data. In order to protect patient privacy, investigators often attempt to “de-identify” the data. This information sheet will briefly explain what PHI is and how to properly de-identify PHI when conducting a research project. If PHI is not properly de-identified (or a signed authorization from the patient is obtained), an investigator may unknowingly violate HIPAA and subject themselves to penalty.

### What is PHI?

Protected health information (PHI) is individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium.

Although HIPAA puts restrictions on the use or disclosure of PHI, the HIPAA regulations do allow researchers to access and use PHI when necessary to conduct research.

For example, PHI is used in research studies involving review of existing medical records for research information, such as retrospective chart review. Also, studies that create new medical information because a health care service is being performed as part of research, such as diagnosing a health condition or a new drug or device for treating a health condition, create PHI that will be entered into the medical record. For example, sponsored clinical trials that submit data to the U.S. Food and Drug Administration involve PHI and are therefore subject to HIPAA regulations.

Some research projects involve health information but the project is not subject to HIPAA. Under the HIPAA Privacy Rule, if health information is de-identified, it is not considered PHI and therefore not subject to the rules and restrictions of HIPAA.

### A data set is considered de-identified only if it does not contain any of these 18 identifiers:

1. Names
2. Geographic subdivisions smaller than a state;
  - Aggregated zip codes consisting of the first three digits of the zip codes, provided that greater than 20,000 individuals live in the area according to the current publicly available data from the Bureau of the Census, may be retained in the data set;
3. Dates directly related to an individual (including but not limited to: date of birth, date of death, date of service)
  - Ages with dates limited to the year of birth, provided that individuals older than 89 years of age are aggregated into one category, may be retained in the data set;
4. Phone numbers;
5. Fax 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 finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)
  - The institution interprets this to include genetic material;

## HIPAA in Research Acknowledgement Form

There are also additional standards and criteria to protect individual's privacy from re-identification. Any code used to replace the identifiers in datasets cannot be derived from any information related to the individual and the master codes, nor can the method to derive the codes be disclosed. For example, a subject's initials cannot be used to code their data because the initials are derived from their name. Additionally, the researcher must not have actual knowledge that the research subject could be re-identified from the remaining identifiers in the PHI used in the research study. In other words, the information would still be considered identifiable if there was a way to identify the individual even though all of the 18 identifiers were removed.

**For more information on HIPAA and acceptable data sets, see HRP-012.**

By my signature, I acknowledge that I have read and understand the information outlined in this document. Furthermore, I certify that I will notify the Franciscan Research Administration (FRA) of any changes to my research project (including modifications to a research dataset).

<b>Name</b>		<b>Department/Specialty</b>	
<b>Signature</b>		<b>Date</b>	