

Saint Louis University
Institutional Review Board
HIPAA TIP SHEET

A. Introduction to HIPAA (the Privacy Rule)¹:

The Privacy Rule is a response to public concern over potential abuses of the privacy of health information. The Privacy Rule establishes a category of health information, referred to as protected health information (PHI), which may be used or disclosed to others only in certain circumstances or under certain conditions. PHI is a subset of what is termed *individually identifiable health information*. With certain exceptions, the Privacy Rule applies to individually identifiable health information created or maintained by a covered entity. Saint Louis University is a covered entity. If researchers are employees or other workforce members of a covered entity (e.g., a covered hospital or university), they have to comply with that entity's HIPAA privacy policies and procedures.

B. Definitions²:

- **Protected Health Information (PHI)** is individually identifiable health information that is a subset of health information, including demographic information collected from an individual, and:
1. Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and
 2. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and
 - i. That identifies the individual; or
 - ii. With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

¹ http://privacyruleandresearch.nih.gov/research_repositories.asp

² <http://www.hipaadvisory.com/action/faqs/glossaryp2.htm>

➤ **Health care** means care, services, or supplies related to the health of an individual. Health care includes, but is not limited to, the following:

1. Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and
2. Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

➤ **Personal identifiers**

The following is a list of 18 Identifiers:

1. Names;
2. Addresses*;
3. Dates**;
4. Telephone numbers;
5. Fax numbers;
6. Email addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan 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***

Research Implications for HIPAA (the Privacy Rule) personal identifiers:

The following is specific information for the personal identifiers (2, 3, and 18) listed above. If collecting personal identifiers with health information (PHI) for research purposes, refer to these definitions to determine whether the address, date or unique identifying number would be considered a personal identifier according to HIPAA (the Privacy Rule).

***Addresses**- All geographical subdivisions smaller than a state, including street address, city county, precinct, zip code, their equivalent geocodes, except for the initial three digits of the zip codes, if according to the current publicly available data from the Bureau of the Censes: (1) geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of the zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

****Dates-** All elements of dates (except year) for the 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.

*****Unique identifying number-** This does not refer to the unique code assigned by the investigator to code the data.

C. Categories of Data Identification:

There are 3 different categories:

1. Identifiable Information- PHI, to which the Privacy Rule applies
2. De-identified- To which the Privacy Rule does not apply
3. Limited Data Set- A middle option, to which limited parts of the Privacy Rule apply

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.

D. Scenarios – Applying HIPAA (the Privacy Rule):

Below is a list of scenarios to provide guidance on how to determine whether or not HIPAA (the Privacy Rule) applies.

1. Questionnaire Scenario:

A survey study will be conducted to assess how medical debt has affected the lives of individuals in Missouri and Kansas. Questions on the survey include questions about the amount of medical debt an individual has, how long they have had it, and if they have made some progress in eliminating the debt. Other questions have to do with other types of debt, whether the person is a homeowner, and some standard demographic questions (income level, marital status, number of children, and race). None of the 18 HIPAA personal identifiers (see above list) are collected. The research is being conducted in areas throughout Missouri and Kansas, and researchers anticipate a minimum of 1,000 participants.

Does HIPAA apply?

No, HIPAA does not apply in this scenario. Even though questions about medical debt are asked, the questions do not elicit information regarding the cause of that debt (no information about treatment or diagnosis is collected), and furthermore, none of the 18 HIPAA personal identifiers are collected. So, PHI is not collected and HIPAA does not apply.

Alteration to Questionnaire Scenario:

If the research in the prior scenario was conducted as an audio-taped interview and questions about the causes of the medical debt were asked, then HIPAA would apply. This is because participants would inevitably relay information about medical treatment that caused their debt, which is considered health information under HIPAA. In addition, because the interview is being audio-taped, the health information is recorded with a personal identifier (see list of personal identifiers, #16). PHI is collected and therefore, HIPAA applies.

2. Questionnaire Scenario:

Research will be conducted to assess physical activity levels & community health needs for the city of St. Louis. A survey will be sent to a random sample of homes in the zip codes 63104, 63106, 63107, 63108, 63115, and 63118. The survey contains questions about individuals' height, weight, and body mass index, frequency and type of physical activity, and about mental and physical health status (including an assessment of diseases that individuals' may have and whether they are currently being treated). The surveys are returned in a self-addressed, stamped envelope to the researcher. No names or addresses of the individuals are collected or recorded.

Does HIPAA apply?

No, HIPAA does not apply in this scenario. Although participants' health information is obtained and recorded, none of the 18 personal identifiers are recorded on the returned surveys. Mailing addresses were known at the time of the initial mailing, but when the surveys are received by researchers, none of the identifiers are present. To generate PHI, you need health information + the identifiers. Since no PHI is generated in this scenario, HIPAA does not apply.

3. Questionnaire Scenario:

Research will be conducted on an adult male graduate student population regarding alcohol use and its impact on school performance. Close-ended questions will be asked regarding types of alcohol consumed, frequency of consumption, and how alcohol use impacts school performance. Birthdates and zip codes are also collected.

Does HIPAA apply?

No, HIPAA does not apply in this scenario. Although sensitive questions regarding alcohol intake are asked and identifiers are collected, specific health information is not collected, so PHI is not generated. If researchers asked if participants had ever been hospitalized as a result of their drinking or had ever completed a treatment program for alcoholism, then PHI would have been generated and HIPAA would have applied.

4. Questionnaire Scenario:

Research will be conducted on a sample of recent immigrants to the United States to assess levels of acculturation and issues facing this population in the metropolitan St. Louis area. Among the survey instruments given to participants is the Beck Depression Inventory (BDI-II), a diagnostic instrument for post-traumatic stress disorder, and instruments to assess acculturation. Participants complete the questionnaires in the researchers' lab and identities of participants are known in case psychiatric intervention must occur with participants who endorse critical items on the Beck Depression Inventory.

Does HIPAA apply?

Yes, HIPAA applies. Mental health information is collected from the participants (diagnostic psychiatric assessments are used in this study), as are personal identifiers. Therefore, PHI is collected and recorded, and HIPAA applies.

5. Focus Group Scenario:

A focus group will be conducted with a group of women to assess their understanding of/knowledge about breast cancer. Questions include common myths and truths about breast cancer, where people find their information about cancer, and whether they have ever been screened for breast cancer/had a mammogram. The focus group session is audio-taped and later transcribed. Once transcribed, the final dataset contains no participant names or other personal identifiers.

Does HIPAA apply?

Yes, HIPAA applies. Because researchers will ask participants if they have ever been screened for breast cancer/had a mammogram, and the information is disclosed to the whole group, protected health information is elicited. Furthermore, since the focus group session is audio-taped, voiceprints are captured on the tapes (and voiceprints are considered a personal identifier under HIPAA). Thus, HIPAA applies.

Alteration to the Focus Group Scenario:

If, in the previous scenario, the women were asked if they believe that breast cancer screenings and routine mammograms are an important part of women's health and wellbeing rather than whether they had ever been screened for breast cancer/had a mammogram, then HIPAA would not apply. The information recorded would have personal identifiers, but there would be no collection of health information specific to the individuals participating in the focus group.

6. Program Evaluation Scenario:

A program evaluation of a healthy cooking course will be conducted and the results published. Participants attending a series of healthy cooking workshop are asked to complete surveys that contain questions about current cooking habits and knowledge of healthy foods. Participants' mailing addresses are collected, along with various demographics such as gender, race, birth date, and marital status. A follow-up survey will be distributed to participants three months after the final workshop to see if participants have incorporated things they learned in the workshops into their daily lives.

Does HIPAA apply?

No, HIPAA does not apply in this scenario. Although identifiers such as address and birth date are collected, no health information is collected. To have Protected Health Information, you need personal identifiers + health information. Since no health information is collected, PHI is not collected and HIPAA does not apply.

7. Secondary Data Analysis Scenario:

A researcher is conducting a secondary analysis of archival data using past research records from a study conducted on population of individuals with bipolar disorder. The data was collected in 1995. The researcher is accessing research records and creating a new data set for analysis purposes. Among the items in the data set are diagnosis information and social security numbers.

Does HIPAA apply?

Yes, HIPAA applies. The researcher is obtaining and recording protected health information (diagnosis data + social security numbers). If the researcher was conducting this study without recording any identifiable information from the medical charts, then HIPAA would not apply to this study.