



FAU Researchers' Guide to HIPAA ¹

The Federal privacy regulations of the Health Insurance Portability and Accountability Act (HIPAA) went into effect on April 14, 2003. As a result, certain researchers and research institutions are required to be in compliance with the HIPAA regulations that are known as the "HIPAA Privacy Rule." Among other provisions, the Privacy Rule sets requirements for the use and disclosure of protected health information (PHI) in research. Updates to this rule, known as the HIPAA/HITECH Omnibus Final Rule, went into effect in March 2013.

What is Protected Health Information (PHI)?

Protected Health Information (PHI) is any "individually identifiable health information" that is created or maintained by a Covered Entity. ([See Assessment Tool 2: Am I Using PHI?](#) for a list of the 18 items that make health information "individually identifiable.")

- PHI is health information *plus* identifiers. It is health information that includes or is able to be linked to the identity of the subject.
- The sources of PHI may be living participants, deceased persons, human tissue samples, databases, or repositories.
- All forms of PHI are protected (i.e., electronic transmissions and media, paper, verbal, tissue samples, photographs, audio/visual recordings).
- In the research environment, PHI can originate from health care services; payment or operations linked to health care services; surveys; interventional clinical studies; clinical assessments; and health records of the deceased.

What is not Protected Health Information (PHI)?

- If the individually identifiable health information is not being created or maintained by a Covered Entity, it is not PHI.
- If data does not contain both 1) health (including mental health) information and 2) identifiers, it is not PHI. A good example is de-identified data that is being used and stored by a Covered Entity.
- PHI that has been disclosed to any entity that is not a Covered Entity is no longer PHI. For example, if a Covered Entity had authorization to disclose PHI to a researcher who is not a Covered Entity, once that researcher has received the PHI, it is no longer PHI and may be used by that researcher without regard to the Privacy Rule.
- Individually identifiable health information that is stored in school records is not PHI.
- Individually identifiable health information that is stored in employee records by a Covered Entity acting in its role as an employer is not PHI.

What is a Covered Entity?

A covered entity is a health care provider, health plan, or health care clearinghouse, but only if they transmit any information in an electronic form to process health care claims and billing.

- Health Care Providers (doctors, hospitals, clinics, dentists, chiropractors, nursing homes, home health agencies, pharmacies, as well as practitioners in psychology, psychotherapy, and social work)
- Health Plans (health insurers, HMOs, company health plans, and government programs such as Medicare, Medicaid, and the military and veterans' health care programs)
- Health Care Clearinghouse (entities that process non-standard health information into a standard electronic format or data content, or vice versa)

Does HIPAA apply to my research study?

The HIPAA Privacy Rule applies only when one or more of the following are true while doing research with human subjects or their identifiable data:

- You use, receive, and/or disclose Protected Health Information (PHI)* from a Covered Entity
- You maintain PHI within a Covered Entity
- You work for a Covered Entity or Covered Component.

For a quick reference to find out if HIPAA applies to your research, see [Assessment Tool 1: Does HIPAA Apply to My Research?](#), available within IRBNet and on our website.

If HIPAA applies to my research, what do I need to do?

If the HIPAA Privacy Rule applies to your research, you must obtain an Authorization to use/disclose PHI or a Waiver of Authorization from either the FAU IRB, a central IRB/Privacy Board utilized by FAU, or from the Covered Entity where the PHI will be obtained.

- If informed consent will be obtained from participants, then the researcher must also obtain a *HIPAA Authorization* from the participants.
- If informed consent has been waived by the IRB and if the study involves the use and disclosure of Protected Health Information (PHI), then the researcher must also obtain a *Waiver of Authorization*.

Both the HIPAA Authorization & Waiver of Authorization form are located in IRBNet.

How is an Authorization Different from Informed Consent?

- An authorization is an individual's signed permission to allow a Covered Entity to use or disclose his/her Protected Health Information for research.
- An informed consent document is an individual's agreement to participate in the research study.

Does HIPAA apply to Exempt studies?

Yes. Studies that are exempt from IRB review are not automatically exempt from the requirements of the HIPAA Privacy Rule. If medical charts will be reviewed retrospectively, identifiable tissue samples will be used, or a clinical/research database or a registry will be accessed during the course of the study, then the researcher must request a Waiver of Authorization from an applicable IRB, Privacy Board, or Privacy Officer. The Waiver of Authorization request and/or approval should be submitted with the IRB application.

Can I obtain an Authorization to use PHI for multiple studies?

Yes. According to the 2013 rule, the authorization does not need to be specific. Rather it must explain each purpose of the requested use or disclosure in such a way that an individual can understand how their PHI could be used and disclosed for future research. *This provision is most applicable to researchers proposing to store information for future research studies.*

If there are both *required* and *optional* components to a study, a researcher can obtain one Authorization provided there is a clear delineation between the required and optional parts of the study. To accomplish this, the consent could have additional signature lines, check-off boxes, or initial lines, for example.

If the hospital or clinic gives patients a "Notice of Privacy Practices," do I still need to get an Authorization to use PHI for research?

Yes. A Notice of Privacy Practices is not the same as an Authorization to use Protected Health Information.

What forms do I use and how?

If you want to obtain PHI from an FAU covered component:

- If the PHI is being obtained prospectively through normal clinical operations, a clinical trial, intervention study, or other research, use a consent form that incorporates the HIPAA authorization language OR provide a separate Authorization form for the participant to sign along with the consent form. These documents should be submitted via IRBNet along with all other required documents for your IRB submission.
- If the PHI is being obtained retrospectively (e.g., via a chart or database review) and you cannot obtain Authorization, submit a request for Waiver or Alteration of Authorization along with your IRB application. If you want to obtain a “limited data set” that involves only certain dates and geographic data (see [Assessment Tool 2: Am I Using PHI?](#)) from the covered entity, you will also be asked to complete and sign a Data Use Agreement.

If you want to obtain PHI from a source outside of FAU (e.g., non-affiliated health care providers, community clinics, social service agencies, etc.), please contact them to find out what HIPAA approval procedures they require, or whether they will defer to FAU’s privacy procedures.

If you want to share (“disclose”) PHI for research purposes, and you are part of an FAU covered component:

1. Ask the requester to provide you with a copy of the IRB approval for the research study.
2. Determine whether the data requested will be de-identified, a limited data set (LDS), or identifiable (see [Assessment Tool 2: Am I Using PHI?](#))
 - a. If data is de-identified, it can likely be released without any further documentation.
 - b. If data being requested meets the criteria of an LDS, obtain a signed copy of the data use agreement from the requester (or his/her authorized official) and submit the agreement to Research Integrity for review/approval.
 - c. If data being requested has identifiers, obtain a copy of the Authorization or Waiver of Authorization request and submit it to Research Integrity for review.
 - d. If you collected the PHI as part of a previous study using a combined consent and authorization document, review the terms of the consent/authorization to confirm that disclosure to others is permitted under those agreements. Contact Research Integrity if you are unsure.
3. If you are disclosing PHI to an outside individual/organization that performs a service on behalf of FAU, a Business Associate Agreement may need to be implemented. Typically, this type of agreement would apply to certain consultants, attorneys, or other paid contractors. Contact Research Integrity or General Counsel for guidance.

For a visual guide to help you decide what forms to submit, click here: [Assessment Tool 3: What HIPAA Forms Do I Use?](#)

Sample Scenarios: Interpreting the HIPAA Privacy Rule

Below is a list of hypothetical scenarios to help you determine whether or not HIPAA (the Privacy Rule) applies to your study. If you have questions and do not see your scenario depicted below, please send an email to researchintegrity@fau.edu.

1. Questionnaire Scenario:

Question: I am a researcher in the College of Business studying how medical debt has affected the lives of individuals in Dade and Broward County. I'd like to conduct telephone surveys with 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 are collected. The research is being conducted via a telephone research company who will contact 1000 random residents. Does HIPAA apply?

Answer: No. 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.

Exception: If the research had been 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 the 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.

2. Questionnaire Scenario:

Question: I would like to survey West Palm Beach residents to assess physical activity levels & community health needs for the city. A survey will be sent to a random sample of homes in the West Palm Beach zip codes. 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?

Answer: No. 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.

3. Questionnaire Scenario:

Question: I'm going to survey adult male graduate students 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?

Answer: No. 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:

Question: I want to survey recent immigrants to St. Lucie & Martin Counties to assess levels of acculturation and issues facing this population. 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 at my FAU 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?

Answer: 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:

Question: 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?

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

Exception: 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:

Question: I plan to conduct a program evaluation of a healthy cooking course and publish the results. Participants attending a series of healthy cooking workshop will be 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?

Answer: 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:

Question: I am conducting a secondary analysis of archival data using past research records from a study of individuals with bipolar disorder. The data was collected in 2005. I will obtain research records and create a

new data set for analysis purposes. Among the items in the data set are diagnosis information and social security numbers. Does HIPAA apply?

Answer: Yes, HIPAA applies. You are obtaining and recording protected health information (diagnosis data + social security numbers). If you were conducting this study without recording any identifiable information from the medical charts, then HIPAA would not apply to this study.

8. Clinical Scenario: Patient Recruitment

Question: I am a faculty member of an FAU covered component (Medicine, Nursing, Student Health). May I review patient records in my clinic to identify possible enrollees in clinical trials conducted in our unit and to speak with the patients about the clinical trials?

Answer: Yes. Physicians and their staff may review their clinic records to identify potential recruits without obtaining a HIPAA authorization, provided that a review of patient records is necessary for this purpose, the information is used solely for this purpose, and neither the clinic records nor any patient-identifiable information is copied or removed from the clinic premises. Treating physicians and their staff may discuss research protocols in which they are involved with their clinical patients without obtaining a HIPAA authorization for that discussion.

9. Clinical Scenario: Medical Record Study (Retrospective Analysis)

Question: I am a medical student/resident and wish to conduct a chart review at No Name hospital for research purposes. I will be working with a physician on staff at the hospital. I will review records of trauma patients admitted in the past 5 years, and will record the patient's medical record number if I need to go back to the record for clarification. Does HIPAA apply?

Answer: Yes. Since the hospital is the holder of the PHI (and thus the "covered entity") you must follow the procedures for obtaining PHI, which will likely involve requesting a Waiver of Authorization unless they defer to FAU's IRB. You will also need IRB approval for your chart review and show evidence that you have obtained appropriate hospital approvals for obtaining PHI.

10. Clinical Scenario: Intervention Study

Question: We would like to conduct a study in our clinic to assess the effect of enhanced communication on diabetes compliance. Half of the patients will receive intervention and half will receive normal care and follow up. We will collect blood glucose, A1C, demographic data, and other variables from both groups, along with their medical record number. The consent form we prepared describes this data collection in the procedures section. Does HIPAA apply?

Answer: Yes. Consent to participate in the research is not the same as Authorization to use protected health information. PHI is being used because it is health data plus identifiers. Therefore, you must use a consent form that includes HIPAA Authorization language.

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