

## **Guidance Regarding Use of Health Records in Research Health Insurance Portability and Accountability Act (HIPAA)**

The Health Insurance Portability and Accountability Act (HIPAA) was passed by Congress in 1996. HIPAA's privacy rule establishes the conditions under which a covered entity can provide researchers access to and use of protected health information when necessary to conduct research.

*Protected health information (PHI)* is any health information, including demographic information collected from an individual, created or received by a health care provider, health plan provider, employer, or health care clearinghouse. It relates to past, present, and future physical, and/or mental health or conditions of individuals, and to the provision of health care to individuals.

### **When does the privacy rule apply to research?**

The HIPAA privacy rule affects research and researchers when:

- Research creates or generates PHI.
- Research requires access to and/or use of PHI.

### **How can PHI be accessed and disclosed for research?**

HIPAA permits use or disclosure of PHI for research under the following circumstances and conditions:

1. The subject of the PHI has granted specific written permission through an authorization form.
  - An authorization form provides a research subject's signed permission to allow a covered entity to use and disclose his/her PHI for research purposes. An authorization form should focus on privacy risks and state how, why, and to whom the PHI will be used, and/or disclosed for research.
  - Obtaining HIPAA authorization is required in addition to obtaining informed consent to participate in research.
  - In the case of minors, a signed authorization form must be obtained from the minor's parent(s) or legal guardian(s).
  - Authorization forms must pertain to specific research studies.
  - Subjects must be given a copy of the signed authorization form to keep for their records.
  - HIPAA regulations require authorization forms to be kept for a minimum of six years from the date they were obtained. Indiana state law requires the retention of medical records for seven years, and thus Butler University recommends signed authorization forms be maintained for seven years.

The HIPAA authorization template can be found at: <https://privacyruleandresearch.nih.gov/authorization.asp>

2. The IRB has granted a waiver of the authorization requirement. The requirement to obtain authorization may be waived if all the following criteria are met:
  - Use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, meaning:
    - An adequate plan is employed to protect the identifiers from improper use and disclosure.
    - An adequate plan is employed to destroy identifying information at the earliest opportunity, consistent with conduct of the research, unless health or research justification for retaining the identifiers exists, or retention is required by law.

- An adequate written assurance is employed, stating the PHI will not be reused or disclosed to any other person or entity, except as required by law for authorized oversight of the research, or for other research to which use/disclosure of PHI would be permitted.
  - The research could not practicably be conducted without the waiver.
  - The research could not practicably be conducted without access to and use of the PHI.
3. The **PHI has been de-identified** in accordance with the standards set by HIPAA, there is no reasonable basis to believe that the data can be used to identify an individual, and the provider has no reasonable basis to believe the data can be used to identify the individual.

Highlighted data fields in the lists below signify data which may NOT be collected for deidentified data sets:

<u>Demographics</u>	<u>Insurance information</u>	<u>Medical information (continued)</u>
Patient identification numbers or cards (SS#, medical record number, drivers license)	<u>Financial information</u>	Procedures
Full name	Insurance carrier	Orders or requests
Street address	Insurance group numbers	Patient history
City, state, zip code	Copy of insurance card	Personal habits
Phone number	Guarantor (responsible party)	Weight
Fax number	Billing address	Height
E-mail address	Employer	Age
URLs and IP addresses>	Primary care provider	Temperature
Gender	Total charges	Pulse
Race	<u>Claim forms</u>	History of present illness
Religion	Payment history	Dictation
Date of birth	Pre-certifications or prior authorizations	Symptoms
Photographs		Physical findings
Spousal information	<u>Medical information</u>	Family medical history
Beneficiary information	Patient complaints	Discharge status
Parent/guardian information	Dates of service	Medications
Emergency contact information	<u>Admission and discharge dates</u>	Barriers to communication
Vehicle identification number	Treating or referring physician, clinic, Hospital	Mode of arrival
Biometric identifiers (including finger and voice prints)	Diagnosis	Allergies/untoward Reactions to drugs
	Treatment Plan	Reason for encounter
	Immunization record	Request for consultation
	Psychotherapy note information	CPT codes
	Lab tests	ICD-9 codes
	Blood type	<u>Date of death</u>

4. Information is released in the form of a limited data set, with certain identifiers removed, and with a data use agreement between the researcher and the covered entity.
- A limited data set excludes facially identifiable information but still includes some identifiable information. As a result, data is still considered identifiable and may be used for limited purposes, including research, public health, or healthcare operations, provided there is a data use agreement in place with the recipient of the limited data set.

Highlighted data fields in the lists below signify data which may NOT be collected for limited data sets:

	<u>Insurance information</u>	
	<u>Financial information</u>	<u>Medical Information (continued)</u>
	Insurance carrier	Procedures
	<u>Insurance group numbers</u>	Orders or requests
<u>Demographics</u>	Copy of insurance card	Patient history
<u>Patient identification numbers or cards (SS#, medical record number, drivers license)</u>	Guarantor (responsible party)	Personal habits
<u>Full name</u>	<u>Billing address</u>	Weight
<u>Street address</u>	<u>Employer</u>	Height
<u>City, state, zip code</u>	Primary care provider	Age
<u>Phone number</u>	Total charges	Temperature
<u>Fax number</u>	<u>Claim forms</u>	Pulse
<u>E-mail address</u>	Payment history	History of present illness
<u>URLs and IP addresses</u>	Pre-certifications or prior authorizations	Dictation
<u>Gender</u>		Symptoms
<u>Race</u>	<u>Medical information</u>	Physical findings
<u>Religion</u>	Patient complaints	Family medical history
<u>Date of Birth</u>	Dates of service	Discharge status
<u>Photographs</u>	Admission and discharge dates	Medications
<u>Spousal information</u>	Treating or referring physician, clinic, Hospital	Barriers to communication
<u>Beneficiary information</u>	Diagnosis	Mode of arrival
<u>Parent/guardian information</u>	Treatment plan	Allergies/untoward reactions to Drugs
<u>Emergency contact information</u>	Immunization record	Reason for encounter
<u>Vehicle identification number</u>	Psychotherapy note information	Request for consultation
<u>Biometric identifiers (including finger and voice prints)</u>	Lab tests	CPT codes
	Blood type	ICD-9 codes
		Date of death