

## What is HIPAA?<sup>1</sup>

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 is legislation that provides data privacy and security provisions for safeguarding medical information. The HIPAA Privacy Rule establishes the conditions under which protected health information (PHI) may be used or disclosed by covered entities for research purposes.

## What does HIPAA have to do with research?<sup>1</sup>

The HIPAA Privacy Rule defines research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” 45 CFR 164.501. The intent of the Privacy Rule is to protect the privacy of individuals identifiable health information, while simultaneously ensuring researchers continue to have access to medical information required to conduct research.

## What if I am collecting HIPAA protected data in my project?<sup>2</sup>

In the course of conducting research, researchers may obtain, create, use, and/or disclose individually identifiable health information. Under the Privacy Rule, covered entities are permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances set forth in the Privacy Rule. Research being conducted that collects

In contrast, an informed consent document is an individual's agreement to *participate* in the research study and includes a description of the study, anticipated risks and/or benefits, and how the confidentiality of records will be protected, among other things. An Authorization can be combined with an informed consent document or other permission to participate in research. If a covered entity obtains or receives a valid Authorization for its use or disclosure of PHI for research, it may use or disclose the PHI for the research, but the use or disclosure must be consistent with the Authorization.

The Authorization must be written in plain language. A copy of the signed Authorization must be provided to the individual signing it if the covered entity itself is seeking the Authorization. The Privacy Rule does not specify who must draft the Authorization, so a researcher could draft one. The Privacy Rule specifies core elements and required statements that must be included in an Authorization. An Authorization is not valid unless it contains all of the required elements and statements. An Authorization form may also, but is not required to, include additional, optional elements so long as they are not inconsistent with the required elements and statements and are not otherwise contrary to the Authorization requirements of the Privacy Rule. An Authorization, whether prepared by a covered entity or by a person requesting PHI from a covered entity, must include the following core elements and required statements:

### **Authorization Core Elements** (see Privacy Rule, 45 C.F.R. §164.508(c)(1))

- Description of PHI to be used or disclosed (identifying the information in a specific and meaningful manner).

- The name(s) or other specific identification of person(s) or class of persons authorized to make the requested use or disclosure.
- The name(s) or other specific identification of the person(s) or class of persons who may use the PHI or to whom the covered entity may make the requested disclosure.
- Description of each purpose of the requested use or disclosure. Researchers should note that this element must be research study specific, not for future unspecified research.
- Authorization expiration date or event that relates to the individual or to the purpose of the use or disclosure (the terms "end of the research study" or "none" may be used for research, including for the creation and maintenance of a research database or repository).
- Signature of the individual and date. If the Authorization is signed by an individual's personal representative, a description of the representative's authority to act for the individual.

**Authorization Required Statements** (see Privacy Rule, 45 C.F.R. § 164.508(c)(2))

- The individual's right to revoke his/her Authorization in writing and either (1) the exceptions to the right to revoke and a description of how the individual may revoke Authorization or (2) reference to the corresponding section(s) of the covered entity's Notice of Privacy Practices.
- Notice of the covered entity's ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the Authorization, including research-related treatment, and, if applicable, consequences of refusing to sign the Authorization.
- The potential for the PHI to be re-disclosed by the recipient and no longer protected by the Privacy Rule. This statement does not require an analysis of risk for re-disclosure but may be a general statement that the Privacy Rule may no longer protect health information.

Sample authorizations can be found at <https://privacyruleandresearch.nih.gov/authorization.asp>

## Can I request to get a waiver for HIPAA authorization?<sup>1</sup>

A covered entity may use or disclose protected health information for research purposes pursuant to a waiver of authorization by an IRB or Privacy Board, provided it has obtained documentation of the following:

- Identification of the IRB or Privacy Board and the date on which the alteration or waiver of authorization was approved;
- A statement that the IRB or Privacy Board has determined that the alteration or waiver of authorization, in whole or in part, satisfies the three criteria in the Rule;
- A brief description of the protected health information for which use, or access has been determined to be necessary by the IRB or Privacy Board
- A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures; and
- The signature of the chair or other member, as designated by the chair, of the IRB or the Privacy Board, as applicable.

The following three criteria must be satisfied for an IRB or Privacy Board to approve a waiver of authorization under the Privacy Rule:

## HIPAA Guidance and IRB

1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
  - a. an adequate plan to protect the identifiers from improper use and disclosure;
  - b. an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
  - c. adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
2. The research could not practicably be conducted without the waiver or alteration; and
3. The research could not practicably be conducted without access to and use of the protected health information.

### Sources:

1. U.S. Department of Health & Human Services. Health information privacy. <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/research/index.html>. Accessed October 2, 2019.
2. National Institute of Health. HIPAA authorization for research. <https://privacyruleandresearch.nih.gov/authorization.asp>. Posted July 18, 2003. Updated July 1, 2004. Accessed October 2, 2019.