

Protecting people who participate in research

*CITI Training Study Guide
Research and HIPAA Privacy Protections*

What is the issue HIPAA addresses?

- If you have access to persons' identifiable health information for any purpose, you are obligated to protect it.
- A researcher using such health information must know the specific limitations that apply, notably those imposed by HIPAA.
- HIPAA regulations supplement FDA and "Common Rule" (general protection of human subjects) regulations

What is HIPAA?

HIPAA requirements were set out in the:
"Health Insurance Portability and
Accountability Act of 1996"

- HIPAA protections focus on "protected health information" (PHI) created in or by health providers and health plans ("covered entities" – organizations covered by the law).
- The intended use of the information determines the rules that will apply.

HIPAA Rules for Research...

Depend on how HIPAA defines research...

- **Research IS** “systematic investigation, including research development, testing, and evaluation, designed to develop and contribute to generalizable knowledge”
- **Research IS NOT:**
 - Quality assessment and improvement activities, outcomes evaluation or development of clinical guidelines (these fall under “health care operations”)
 - Research activities that aim for population health knowledge (these fall under “public health activity”)
- **Determination is made by IRB or legal counsel**

HIPAA Rules for Research

When a health plan or provider shares information, it may rely on an IRB to assess compliance with HIPAA

- **Generally HIPAA requires explicit written authorization by the person (subject) whose information is to be used.**
- **There are exceptions, but these exceptions require a waiver approved by the IRB (similar to a waiver of informed consent).**

HIPAA Rules for Research

- **Exceptions (grounds for waivers) include:**
 - **There is “minimal risk” to the privacy of the research subject**
 - **The information will not leave the health providers’ premises and will be used only for reviews preparatory to research**
 - **The person is deceased**
 - **Recruitment activities “preparatory to research” so long as the PHI does not leave the health provider premises**

HIPAA Rules for Research

- **Other Exceptions (grounds for waiver of subject's authorization):**

- The information is fully de-identified (anonymized) (When information is in no way individually identifiable and there is no way to re-identify it, it is no longer "PHI".)
- The PHI of subjects is provided by the health organization as a "limited data set" with a "data use agreement" that sets out permitted users and uses and requires recipients not to re-identify the data or contact the individuals.

HIPAA Rules for Research

- **When exceptions apply...**

- Uses and disclosures of data for research must meet the "minimum necessary" standard – the uses/disclosures must be no more than the minimum required for the described research purpose.
- An IRB may determine that the information requested is the minimum necessary for the research purpose.

HIPAA Rules for Research

However, subjects have rights even under these exceptions:

- The right to an "accounting of disclosures."
- The health organization is obligated to disclose to the subject any researchers and research projects using the person's information
- More detailed information must be disclosed if the research involved fewer than 50 subject records.

HIPAA Rules for Research

When subjects do authorize the use of their information:

- Authorizations must be in plain language so that the subject can make an informed decision.
- Authorizations must be in writing, signed by the research subject.
- Usually authorizations will have an explicit expiration date or event (such as “the end of the study”)

HIPAA Rules for Research

DHHS encourages that authorizations include:

- How PHI may be used and disclosed
- Sources of funding for the study and payment arrangement for investigators
- Any information that might affect the subject’s decision to participate

HIPAA Rules for Research

Who should a researcher consult with if there are questions about HIPAA’s research requirements?

Depending on the issue:

- ✦ The IRB
- ✦ The Privacy Board
- ✦ The Privacy Officer
- ✦ The Security Officer
