HIPAA Frequently Asked Questions

What are examples of protected health information (PHI)?

1. Name
2. All geographic subdivisions smaller than a state (street address, city, county, precinct) Note: zip code or equivalents must be removed, but can retain first 3 digits if the geographic unit to which the zip code applies if the zip code area contains more than 20,000 people
3. For dates directly related to the individual, all elements of dates, except year. (date of birth, admission date, discharge date, date of death)
4. All ages over 89 or dates indicating such an age
5. Telephone number
6. Fax number
7. Email address
8. Social Security Number
9. Medical Record Number
10. Health Plan Number
11. Account Numbers
12. Certificate or license numbers
13. Vehicle identification/serial numbers, including license plate numbers
14. Device identification/serial numbers
15. Universal Resource Locators (URLs)
16. Internet Protocol (IP) addresses
17. Biometric Identifiers
18. Full face photographs and comparable images
19. Any other unique identifying number, characteristic or code

When is health-related information considered PHI?
Health-related information is considered PHI if (any of the following are true):

1. the researcher obtains it directly from a provider, health plan, health clearinghouse or employer (other than records relating solely to employment status);
2. the records were created by any of the entities in "1" and the researcher obtains the records from an intermediate source which is NOT a school record or an employer record related solely to employment status; OR
3. the researcher obtains it directly from the study subject in the course of providing treatment to the subject.

Health-related information is not considered PHI if the researcher obtains it from:

- student records maintained by a school;
- employee records maintained by an employer related to employment status; OR
- the research subject directly, if the research does NOT involve treatment.

Are any health records exempted from the definition of PHI?
The following records ARE EXEMPTED from the definition of PHI even though they may contain health-related information:

1. student records maintained by an educational institution

2. employment records maintained by an employer related to employment status.

Studies that use these kinds of records are not subject to HIPAA. However, existing IRB rules on informed consent and confidentiality still apply.

What can a limited-data set include?

- Dates of birth
- Dates of death
- Dates of service
- Town or city
- State
- Zip code

Is a HIPAA Authorization the same as the consent form?
No. An Authorization differs from an informed consent in that an Authorization focuses on the privacy risks and states how, why, and to whom the PHI will be used and/or disclosed for research. An informed consent, on the other hand, provides research subjects with a description of how the confidentiality of records will be protected, among other things.
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How do I qualify for a waiver of authorization?
Approvals for waivers or alterations will be rare and in most cases researchers are advised to use an Authorization Form with their subjects to use/disclose PHI. IRB approval is required for this Authorization Form similar to consent forms.

The following criteria must be met to qualify for a waiver:

- The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;
- An adequate plan to protect the identifiers from improper use and disclosure;
- 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
- 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 study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
- The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;
- The research could not practicably be conducted without the alteration or waiver or alteration; and
- The research could not practicably be conducted without access to and use of the protected health information.

The IRB maintains the authority to make the final decision if a study meets the aforementioned criteria.

Do minors need to sign a separate HIPAA authorization?
Yes. The minor's parent or legal guardian must sign a HIPAA authorization on the minor's behalf.

You can use the same HIPAA authorization for minors that you would use for adults. HIPAA does NOT have an added assent requirement for minors.

Do subjects receive a copy of the Authorization Form as they do a consent form?
Yes, but subjects must receive a signed copy of the authorization.

Can authorization be revoked by the subject?
Yes, a subject can revoke his/her authorization at any time in writing. Data already collected under the authorization can be used to a limited extent if necessary to preserve the integrity of the research.

What about reviews preparatory to research?
Reviews preparatory to research do not require subject authorization. However, this determination must be made by the IRB.

What about data that is de-identified?
Researchers may use or disclose health information that is de-identified without restriction under the Privacy Rule. Covered entities seeking to release this health information must determine that the information has been de-identified using either statistical verification of de-identification OR by removing the 19 identifiers from each record as specified in the Privacy Rule.