

My research involves only de-identified data, so why should I be concerned about the HIPAA Privacy Rule?

Data that is considered de-identified today may not be considered de-identified when HIPAA takes effect. The privacy rule names 18 separate identifiers that must be removed from patient records before that information can be considered de-identified. You will need to consider whether the resulting data will be of use once this information is removed.

Covered entities have the option of stripping fewer identifiers from patient records but only if an expert with knowledge of statistical and scientific principles and methods assures that patients will not be identifiable from the disclosed data or by comparison of the data with other sources of information.

Another option is to obtain a limited data set. This data set can contain more information about subjects, such as dates of birth and 5-digit zip codes, than de-identified data. This disclosure requires a Data Use Agreement between you and the covered entity that establishes the permitted uses and disclosures of the data set.

Alternatively, you can apply for a waiver from your school's IRB, as discussed in the previous section.

How do I learn more about my HIPAA compliance obligations?

To learn more about HIPAA, call your school's IRB administrator or one of the other contacts listed on the back panel of this pamphlet.

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HIPAA PRIVACY RULE

Are You Ready for the Health Insurance Portability & Accountability Act (HIPAA) Privacy Rule?

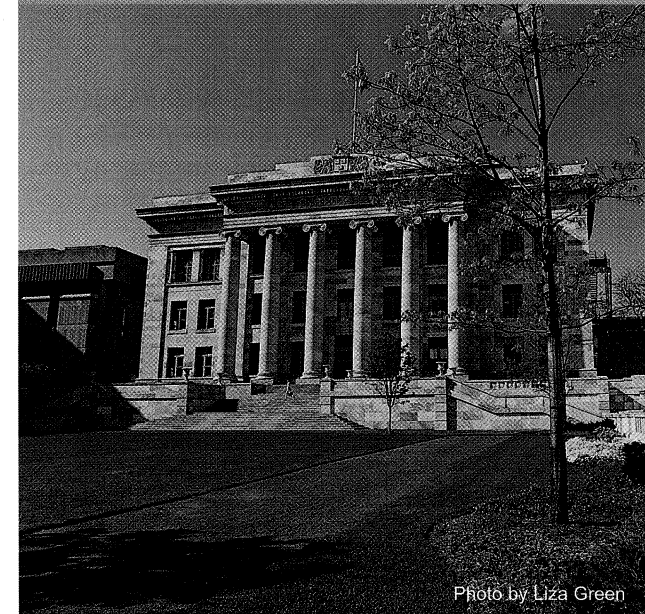


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Take the HIPAA Challenge

What is the HIPAA Privacy Rule?

This is a federal law that protects the privacy of individually identifiable health information, such as medical history, diagnosis, treatment, or payment information. Protected information also includes demographic information, such as date of birth and social security number, that is maintained with health information. The protection applies to all forms of information, including electronic and paper.

This law was created in response to the growing anxiety among Americans about the use and dissemination of health information in an age when computers allow easy sharing of data. Although HIPAA will present challenges to researchers who study health issues, Harvard's compliance efforts should be viewed as an opportunity to demonstrate to the public that scientists treat confidential health information responsibly.

Will the HIPAA Privacy Rule affect my research?

Yes, if you collect health information, whether about individuals or in aggregate form, from any of the following:

- Health care providers, including hospitals;
- Health plans, including insurance companies; or
- Health care clearinghouses, including third party administrators of health plans.

Under HIPAA, these groups are considered "covered entities" and are limited in their ability to share individually identifiable health information with researchers.

How could the HIPAA Privacy Rule affect my research?

After April 2003, covered entities will **not** be able to share health information with you **unless**:

- The covered entity first obtains from each patient whose information is to be disclosed a written authorization to share that information with you;
- Your school's IRB or the covered entity's IRB approves a waiver of patient authorization;
- The covered entity "de-identifies" the health information before disclosing it to you; or
- The covered entity shares only a "limited data set" under the terms of a Data Use Agreement that meets HIPAA requirements.

Under the HIPAA Privacy Rule, covered entities will be required to keep a record of certain releases of health information for research purposes. Covered entities will also be required to give patients, upon their request, an accounting of all such disclosures. These new requirements could make obtaining data from covered entities more challenging after April 2003.

If the HIPAA Privacy Rule does not take effect until April 2003, why should I worry about it now?

If you are conducting longitudinal studies involving patient health information, you may want to begin obtaining patient authorizations sooner rather than later to assure the use of data collected after April 2003 in the event subjects later become unreachable.

If you intend to obtain patient information that will be created by a particular covered entity before and after April 2003, you should consider contacting the covered entity at the earliest opportunity about obtaining patient authorizations.

In the meantime, your school's IRB has begun preparing materials to assist you in meeting the new standards. These materials will be available well before the compliance date.

Are there any exceptions to the HIPAA Privacy Rule?

Yes, there are several exceptions. For example:

- A covered entity may share information with you concerning deceased patients if you meet certain criteria.
- A covered entity may permit you access to health information to assist you in designing a research protocol provided certain conditions are satisfied.

Your school's IRB will assist you in identifying other relevant exceptions.