



National Human Genome Research Institute

## Privacy Protections for Biomedical Research Participants

Broad public participation in research is critical to advancing genomic science and precision medicine. To maximize research participation, robust privacy protections for personal health information must be in place. At the same time, data sharing capabilities among researchers maximizes the utility of participant data, which promotes scientific progress and medical discoveries.

When individuals participate in federally funded research, several laws and regulations balance these competing priorities, protect information, and ensure that participants understand how their private health information will be used:

- **The Common Rule** regulates most federally funded human subjects research, including academic biomedical research. The U.S. Food and Drug Administration (FDA) has its own human subjects research regulations for clinical investigations that closely align with the Common Rule.
- In clinical research, the **Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule** protects the confidentiality of patients' individually identifiable health information held by healthcare providers and other HIPAA-covered entities.

### Researchers must obtain authorization from participants in order to collect, use, or disclose identifiable health information for some types of research.

- **Informed consent:** Both the Common Rule and HIPAA require researchers to obtain meaningful informed consent from each participant prior to their participation. Participants must be informed of potential risks associated with the release of their private health information and who will have access to their information.
- **Secondary research:** Researchers must obtain specific consent to broadly use an individual's identifiable health information for additional research beyond the initial study.
- **De-identification:** If a person's health information can be stripped of personal identifiers, then the Common Rule or HIPAA no longer cover the information and consent is not required.



For more information:  
[www.genome.gov/privacy](http://www.genome.gov/privacy)

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## What information is protected from disclosure in the clinic?

Outside of research, HIPAA protects health information. Protected health information includes private information (e.g., demographic data), health information (e.g., medical records, test results or bills) and biospecimens (e.g., blood or tissue samples) that are identifiable, meaning the data is linked to individual identifiers.

The Genetic Information Nondiscrimination Act (GINA) amended HIPAA to establish that genetic information is protected health information and to prevent the disclosure or use of genetic information by health insurance companies for underwriting purposes.

## When is a research participant's health information protected?

- **Legal proceedings:** Certificates of Confidentiality are automatically issued for federally funded research that uses identifiable, sensitive information. These Certificates impose a requirement for investigators and institutions to withhold identifying information in civil, criminal or other proceeding at federal, state or local levels.
- **FOIA exemption:** The Public Health Services Act includes a Freedom of Information Act (FOIA) exemption for biomedical information collected for research purposes. The Secretary of HHS can invoke this exemption at his or her discretion when there is even a small risk that an individual could be identified from the requested information. This definition includes genetic information

## A research participant's health information may NOT be protected—

- When the health information is de-identified. For example, genomic data that is not linked to other personal identifying information is not subject to regulation. In this case, risks to participants are low as they cannot be identified from the data.
- Under certain circumstances to protect public health. For example, an individual's protected health information may be disclosed to:
  - public health authorities for the purposes of preventing or controlling disease.
  - a person subject to FDA jurisdiction, for purposes related to the quality, safety or effectiveness of an FDA-regulated product.
- When the research is wholly privately funded, does not involve a HIPAA-covered entity and is not part of a clinical investigation of products under FDA jurisdiction.
- When an Institutional Review Board (IRB) grants a waiver of participants' authorization for use/disclosure, such as when there is minimal risk to the privacy of individuals and consent is not practical.



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