

Genetic Information Nondiscrimination Act (GINA)

Overview:

This guidance is specific to research involving genetic testing. The Genetic Information Nondiscrimination Act of 2008 ([GINA](#)) is a Federal law that prohibits discrimination in health coverage and employment based upon genetic information.

This guidance is intended to describe:

What content, relating to GINA, should appear in consent and other study documents

Definitions:

Genetic test is defined as an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detect genotypes, mutations, or chromosomal changes.

A **manifest disease or disorder** refers to an ailment that is apparent through the appearance of symptoms that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine.

Genetic information is defined as information about:

- An individual's genetic tests (including genetic tests done as part of a research study);
- Genetic tests of an individual's family members (defined as dependents and up to and including 4th degree relatives);
- Genetic tests of any fetus of an individual or family member who is a pregnant woman, and genetic tests of any embryo legally held by an individual or family member utilizing assisted reproductive technology;
- The manifestation of a disease or disorder in an individual's family members (family history); or
- Any request for, or receipt of, genetic services or participation in clinical research that includes genetic services (genetic testing, counseling, or education) by an individual or an individual's family members.

*Genetic information does not include information about the sex or age of any individual.

Genetic Information Nondiscrimination Act (GINA)

GINA is a federal law that prohibits discrimination in health coverage and employment based on genetic information.

**GINA does not cover genetic testing for already manifest diseases and disorders or pathological conditions that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine. GINA only covers genetic testing of diseases and disorders that have not yet manifest.*

Informed Consent

When investigators develop consent processes and documents for genetic research, they should consider whether and how the protections provided by GINA should be reflected in the consent document's description of risks and provisions for assuring the confidentiality of the data.

Investigators must ensure that descriptions of the reasonably foreseeable risks of genetic research and any statements describing the extent to which confidentiality of records identifying the subject will be maintained do not overstate the protections provided by GINA (45 CFR 46.116(a)).

Below is suggested sample language investigators should consider including in their consent document, if appropriate:

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law will protect you in the following ways:

- *Health insurance companies and group health plans may not request your genetic information that we get from this research.*
- *Health insurance companies and group health plans may not use your genetic information that we get from this research when making decisions regarding your eligibility or premiums.*
- *Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.*

Be aware that this new federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by all employers.

For genetic research that involves determining whether subjects have an already manifest genetic disease or disorder, investigators should consider including additional language in the informed consent document indicating that GINA does not prohibit discrimination on the basis of an already manifest genetic disease or disorder.

Additional Resources:

<http://ghr.nlm.nih.gov/spotlight=thegeneticinformationnondiscriminationactgina>