

The Genetic Information Nondiscrimination Act—or GINA—is a federal law that prohibits health insurance companies and employers from discriminating based on genetic information. Together with certain provisions of HIPAA, GINA generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of individuals or members of their family, or from basing decisions about coverage, rates, or preexisting conditions on genetic information. GINA also prohibits employers from using genetic information to make decisions about hiring, firing, promotion, or terms of employment.

Many states have passed their own laws to protect against genetic discrimination by health insurers and employers. GINA's protections represent the federal government's minimum protection standard. Entities subject to GINA must comply with applicable GINA requirements, and may also need to comply with state laws, whose protections may extend beyond GINA's.

Under GINA, the term *genetic information* refers to:

- an individual's genetic tests, in both clinical and research contexts;
- genetic tests of an individual's family members, including fetuses and embryos;
- a disease or disorder in an individual's family; or
- any clinical or research-related genetic services—including genetic testing, counseling, or education—that an individual or family member requests or receives.

GINA defines a *genetic test* as an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detect genotypes, mutations, or chromosomal changes. Routine tests that do not detect genotypes, mutations, or chromosomal changes—for example, complete blood counts, cholesterol tests, and liver enzyme tests—are not considered genetic tests under GINA.

GINA's definition of *genetic information* does not include information about an individual's sex or age.

GINA's protections against genetic discrimination by health insurers do not extend to life insurance, disability insurance, or long-term care insurance. Subjects in research may face risks of genetic discrimination by these types of insurance providers.

Although GINA generally prohibits health insurers from requesting that individuals undergo genetic testing, it permits an exception for health insurers engaged in research. Such insurers may request—though not require—a genetic test in connection with the research, provided:

- that research activity complies with federal regulations governing human subjects research, as well as all applicable state or local laws;

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- that the request, which must be in writing, makes it clear to subjects that genetic testing is voluntary and that refusing to undergo testing will have no effect on eligibility for benefits or premium or contribution amounts; and
- that the insurer will not use the genetic information for underwriting purposes.

During initial and continuing review of genetic research, IRBs should consider whether consent documents and discussions ought to include information about GINA. If so, IRBs should make sure the information accurately reflects GINA's protections. IRBMED's informed consent templates include recommended GINA language.

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Contact the IRB for more information about GINA.

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