

Quick Guide to GINA (the Genetic Information Nondiscrimination Act)

What is the status of GINA?

- GINA is a federal law prohibiting health insurers and employers from discriminating based on genetic information that was signed into law on May 21, 2008.
- Regulations interpreting the law are currently being drafted and will be available within 12 months (by May 2009).
- The health insurance provisions of GINA take effect in May 2009, while the employment provisions take effect six months later in November 2009.

What GINA does

- Prohibits group and individual health insurers from using a person's genetic information in determining eligibility or premiums
- Prohibits an insurer from requesting or requiring that a person undergo a genetic test
- Prohibits employers from using a person's genetic information in making employment decisions such as hiring, firing, job assignments, or any other terms of employment
- Prohibits employers from requesting, requiring, or purchasing genetic information about a person or his or her family members
- The law will be enforced by the Departments of Health and Human Services, Labor, and Treasury, along with the Equal Opportunity Employment Commission. Remedies for violations include corrective action and monetary penalties.

What GINA does not do

- Does not mandate coverage for any particular test or treatment
- Does not prohibit medical underwriting based on current health status
- Does not cover life, disability, or long-term care insurance
- Does not apply to members of the military

Key Terms

Genetic information includes information about:

- a person's genetic tests or those of his or her family members (up to and including fourth-degree relatives)
- any manifestation of a disease or disorder in a family member (family history)
- participation of a person or family member in research that includes genetic testing, counseling, or education

Genetic tests means tests that assess genotypes, mutations, or chromosomal changes.

Examples of protected tests are:

- *BRCA1/BRCA2* (breast cancer) or *HNPCC* (colon cancer) mutations
- classification of genetic properties of an existing cancer tumor to help determine therapy
- Huntington's disease mutations
- Carrier screening for disorders, such as cystic fibrosis, sickle cell anemia, spinal muscular atrophy, and fragile X syndrome
- Routine tests such as complete blood counts, cholesterol tests, and liver-function tests are not protected under GINA.

What does GINA mean for IRBs?

- When the law takes effect (May 2009 and November 2009), prospective study subjects should be informed about the scope and limitations of GINA.
- Language to address the risks of discrimination based on genetic information should likely be amended in most consent templates, with care taken not to overestimate the protections afforded by GINA – it is important to note that there are no protections for life, disability, or long-term care insurance.