# Summary of Genetic Information Nondiscrimination Act of 2008 (GINA)
# Public Law 110-233

## Title II: Genetic Nondiscrimination in Employment

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| Section 201<br><br>**Definitions** | Commission–means Equal Employment Opportunity Commission<br><br>Employee – means an employee (including an applicant) as defined by<br><br>a) Section 701(f) and 717(a) of the Civil Rights Act of 1964<br>b) Section 304(a) of the Government Employee Rights Act of 1991 (State employees)<br>c) Section 101 of the Congressional Accountability Act of 1995 (Covered employee)<br>d) Section 411(c) of title 3, U.S.C (Covered employee)<br><br>Employer – means an employer as defined by<br><br>a) Section 701(b) and 717(a) of the Civil Rights Act of 1964<br>b) Section 304(a) of the Government Employee Rights Act of 1991 (State entity employing state employee)<br>c) Section 101 of the Congressional Accountability Act of 1995 (Employing Office)<br>d) Section 411(c) of title 3, U.S.C (Employing Office)<br><br>Employment Agency; Labor Organization – meanings as defined bySection 701 of the Civil Rights Act of 1964 (member of labor organization includes applicant for membership)<br><br>Family Member – with respect to an individual includes a dependent and any other first-degree, second-degree, third-degree, or fourth-degree relative of such individual or their dependent.<br><br>Genetic Information – means with respect to any individual information about such individual's genetic tests, the genetic tests of family members of such individual, and the manifestation of a disease or disorder in family members of such individual. It shall also include, with respect to any individual, any request for or receipt of genetic services or participation in clinical research, which includes genetic services by such individual or any family member of such individual. It shall not include information about the sex or age of any individual.<br><br>Genetic Monitoring – means the examination of employees to evaluate acquired modifications to their genetic material (such as chromosomal damage or evidence of increased occurrence of mutations) that may have developed as the result of exposure to toxic substances in the workplace in order to identify, evaluate, and respond to the effects of or control adverse environmental exposure in the workplace.<br><br>Genetic Services – means a genetic test, genetic counseling (inc. obtaining, interpreting, or assessing genetic information), and genetic education.<br><br>Genetic Test – means an analysis of human DNA, RNA, | Definitions are consistent with existing civil rights laws<br><br>Employee means any individual employed by an employer<br><br>Employer means a person engaged in an industry affecting interstate commerce who has 15 or more employees<br><br>Employment Agency– means any person regularly undertaking with or without compensation to procure employees for an employer<br><br>Same def. as Title I: inc. siblings, parents, children, aunts/uncles, grandparents, grandchildren, cousins, great grandparents and cousins once removed<br><br>Definition includes family history which could be used to identify genetic information. Most state employment statutes limit their protections to the results of genetic tests only |

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| | chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes. It does mean such analyses that do not detect genotypes, mutations, or chromosomal changes. | |
| Section 202<br><br>**Employer Practices** | DISCRIMINATION BASED ON GENETIC INFORMATION<br><br>It shall be an unlawful employment practice for an employer to refuse to hire, or to discharge, any employee, or otherwise to discriminate against any employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, because of genetic information with respect to the employee; or to limit, segregate, or classify the employees of the employer in any way that would deprive or tend to deprive any employee of employment opportunities or otherwise adversely affect the status of the employee as an employee because of genetic information with respect to the employee. | The prohibitions for employers cover the entire range of ways in which an employee could claim discrimination, from hiring decisions to employee status |
| | ACQUISITION OF GENETIC INFORMATION<br><br>It shall be an unlawful employment practice for an employer to request, require, or purchase genetic information with respect to an employee or family member of an employee except | Subject to the below exceptions, this is a total ban that will affect an employer's ability to access such information, even in cases where the ADA would have permitted it as part of a request for reasonable accommodation or as part of a medical evaluation after a conditional offer of employment has been made. This prohibition applies even in cases where the information may be job related. |
| | a) Where an employer inadvertently requests or requires family medical history of the employee or family member of the employee. | This provision is meant to address so called "water cooler" conversations, where an employee might voluntarily disclose genetic info to the employer in the course of an otherwise innocent interaction. This exception applies only to family history, not to all forms of genetic information |
| | b) Where health or genetic services are offered by the employer, including such services offered as part of a wellness program; the employee provides prior, knowing, voluntary, and written authorization; only the employee (or family member if the family member is receiving genetic services) and the licensed health care professional or board certified genetic counselor involved in providing such services receive individually identifiable information concerning the results of such services and such information is only available for such services; and such information shall not be disclosed to the employer except in | Many employer wellness programs begin with some form of health questionnaire. Specific authorization from the employee will be required to be in compliance. |

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| | aggregate terms that do not disclose the identity of any specific employee.<br><br>c) Where an employer requires family medical history from the employee to comply with the certification provisions of Section 103 of the FMLA or such requirement under State family and medical leave laws.<br><br>d) Where an employer purchases documents that are commercially and publicly available (inc. newspapers, magazines and books, but not including medical databases or court records) that include family medical history.<br><br>e) Where the information involved is to be used for the genetic monitoring of the biological effects of toxic substances in the workplace, but only if: the employer provides written notice to the employee, the employee provides prior, knowing, voluntary and written authorization or the genetic monitoring is required by Federal or State law, the employee is informed of the individual monitoring results, the monitoring is in compliance with Federal genetic monitoring regulations inc. those promulgated by the Secretary of Labor or State regulations under OSHA, the Federal Mine Safety and Health Act or the Atomic Energy Act, and the employer (excluding any licensed health care professional or board certified genetic counselor) receives the results of the monitoring only in aggregate terms that do not disclose the identity of the individual employee.<br><br>f) Where the employer conducts DNA analysis for law enforcement purposes as a forensic laboratory or for purposes of human remains identification, and requests or requires genetic information of such employer's employees, but only to the extent that such genetic information is used for analysis of DNA identification markers for quality control to determine sample contamination.<br><br>Preservation of Protections – In the event genetic information is acquired as a result of any of these exceptions it may not be used to discriminate, for any use leading to additional acquisitions of genetic information is subject to limitations on disclosure (sec. 206). | An employer may require that a request for leave be supported by a certification issued by the health care provider<br><br>This exception applies only to family history, not to all forms of genetic information<br><br>Some employers conduct genetic tests of workers in specific hazardous environments to determine if there is a hazardous breach or if workers need to be reassigned before they become symptomatic of adverse exposure. An employee cannot be required to submit to such testing but could likely be reassigned if the cost to the employee was not so high as to render his possible change of mind involuntary. Nevertheless, employment cannot be denied because of increased occupational risk. This provision does not affect employees with a current medical condition. |
| Section 203<br><br>**Employment Agency Practices** | Identical to Section 202 | |
| Section 204 | Identical to Section 202 | |

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| **Labor Organization Practices** | | |
| Section 205<br><br>**Training Programs** | Applies to employers, labor organizations, or joint labor-management committees controlling apprenticeship or other training or retraining programs, inc. on-the-job training programs.<br><br>Identical to Section 202 | |
| Section 206<br><br>**Confidentiality of Genetic Information** | <u>TREATMENT OF INFORMATION AS PART OF CONFIDENTIAL MEDICAL RECORD</u><br><br>If an employer, employment agency, labor organization, or joint labor-management committee possesses genetic info about an employee or member, such information shall be maintained on separate forms and in separate files and be treated as a confidential medical record. Such entities shall be considered to be in compliance with this requirement if such info is maintained with and treated as a confidential medical record under section 102(d)(3)(B) of the Americans with Disabilities Act.<br><br><u>LIMITATION ON DISCLOSURE</u><br><br>An employer, employment agency, labor organization, or joint labor-management committee shall not disclose genetic information concerning an employee or member except:<br><br>a) To the employee or member (or family member if the family member is receiving the genetic services) at the written request of the employee or member of such organization.<br><br>b) To an occupational or health researcher if such research is conducted in compliance with part 46 of Title 45, Code of Federal Regulations.<br><br>c) In response to a court order, except that-<br><br>1. Covered entities may only disclose the genetic info expressly authorized by the order.<br><br>2. If the court order was secured without the knowledge of the employee or member to whom the information refers, covered entities shall inform the employee or member of the court order and any genetic info that was disclosed pursuant to such.<br><br>d) To government officials who are investigating compliance with this title if such information is relevant to the investigation.<br><br>e) To the extent disclosure is made in connection with the employee's compliance with the certification provisions of Section 103 of the FMLA or such requirement under State family and medical leave laws.<br><br>f) To a Federal, State, or local public health agency only with regard to information about the manifestation of a disease or disorder in family members of such individual and that concerns a contagious disease that presents an imminent hazard of death or life-threatening illness and the employee whose family member is the subject of such disclosure is notified of the disclosure. | GINA does not require employers to keep separate medical files solely for genetic information. Rather, genetic information can be maintained with general health information, and the confidentiality of the aggregate is governed by HIPAA.<br><br>GINA does not permit disclosure of genetic information in response to a subpoena or discovery request.<br><br>An employer may require that a request for leave be supported by a certification issued by the health care provider |

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| | RELATIONSHIP TO HIPAA REGULATIONS<br><br>This title does not prohibit a covered entity under the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act and Section 264 of HIPAA from any use or disclosure of health information that is authorized for such covered entities; this does not affect the authority of such Secretary to modify such regulations. | Refers to HIPPA Privacy Rule (recommendations on standards with respect to the privacy of individually identifiable health information) |
| Section 207<br><br>**Remedies and Enforcement** | Employees covered by<br><br>a) Title VII (and section 717) of the Civil Rights Act of 1964<br>b) Government Employee Rights Act of 1991<br>c) Congressional Accountability Act of 1995<br>d) Chapter 5 of Title 3 of the U.S. Code<br><br>shall have the powers, procedures, and remedies provided by the aforementioned sections ( inc. provisions regarding costs and fees and damages).<br><br>PROHIBITION AGAINST RETALIATION<br><br>No person shall discriminate against any individual because such individual has opposed any act or practice made unlawful by this title or because such individual made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this title. The remedies and procedures otherwise provided for in this section shall be available to individuals with respect to violation of this section. | Remedies and enforcement are consistent with existing civil rights laws<br><br>EEOC exhaustion is required before an employee can pursue a private civil action. The framework of caps for compensatory and punitive damages is:<br><br>15-100 Employees: $50,000<br>101-200 Employees: $100,000<br>201-500 Employees: $200,000<br>Over 500 Employees: $300,000<br><br>All penalties are maximum |
| Section 208<br><br>**Disparate Impact** | "Disparate impact" (as defined by the Civil Rights Act of 1964) on the basis of genetic information does **not** establish a cause of action under this Act.<br><br>COMMISSION<br><br>a) Six years after the enactment of this Act, the Genetic<br><br>Nondiscrimination Study Commission shall be established to review the developing science of genetics and make recommendations to Congress regarding whether to provide a disparate impact cause of action under this Act.<br><br>b) The Commission shall be composed of eight members with one member each appointed by the Senate Majority and Minority | Disparate impact is a theory of liability that prohibits an employer from using a facially neutral employment practice that has an unjustified adverse impact on members of a protected class. A facially neutral employment practice is one that does not appear to be discriminatory on its face; rather, it is one that is discriminatory in its |

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| | Leaders, Chairman and ranking minority member of the Senate<br><br>HELP Committee, Speaker and Minority Leaders of the House of Representatives, Chairman and ranking minority member of the Education And Labor Committee. These members shall not receive compensation but shall be allowed travel expenses, inc. per diem, while away from their homes or regular place of business in performance of Commission duties in accordance with subchapter I, chapter 57 of title 5 USC.<br><br>c) The Commission shall be located in a facility maintained by the EEOC and such sums are authorized to be appropriated to the EEOC as necessary to carry out this section. Any Federal employee may be detailed to the Commission without reimbursement or loss of civil status. The Commission may secure such information as necessary to carry out the provisions of this section and the head of such departments shall furnish such information that is requested. The Commission may hold hearings, take testimony and receive evidence as the Commission requires to carry out its duties. To the extent possible, the Commission shall use existing data and research and may use US mail under the same conditions as other Federal agencies.<br><br>d) No later than one year after all the members are appointed to the Commission they shall submit to Congress a report that summarizes their findings and makes recommendations for legislation consistent with this Act. | application or effect |
| Section 209<br><br>**Construction** | Nothing in this title shall be construed to **–**<br><br>a) Limit the rights or protections of an individual under any other Federal or State statute that provides equal or greater protection to an individual than is provided under this Act, inc. the Americans with Disabilities Act and the Rehabilitation Act of 1973.<br><br>b) Limit the rights or protections of an individual to bring an action under this title for a violation; or provide for enforcement of, or penalties for, a violation of any requirement or prohibition applicable to any covered entity subject to enforcement for a violation under Title I of this Act.<br><br>c) Apply to the Armed Forces Repository of Specimen Samples for the Identification of Remains.<br><br>d) Limit or expand protections or obligations under worker's compensation laws.<br><br>e) Limit the authority of a Federal department or agency to conduct occupational or other health research in compliance with part 46 of title 45, Code of Federal Regulations (or corresponding | This is the so-called firewall provision of GINA. It prevents claims originating from adverse actions under Title I (health insurance) from being used as the basis of a claim against an employer. It is likely, though, that directed actions taken by an employer implicating health insurance would remain actionable under this title. |

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| | regulations).<br><br>f) Limit the statutory or regulatory authority of OSHA or MSHA to promulgate and enforce workplace health and safety laws or regulations.<br><br>g) Require any specific benefit under a group health plan or health insurance issuer offering group coverage in connection with a group health plan.<br><br><u>GENETIC INFORMATION OF A FETUS OR EMBRYO</u><br><br>Any reference to genetic information in this title concerning an individual or family member of such shall include genetic information of any fetus with respect to such individuals if a pregnant woman or any embryo legally held as a result of utilization of assisted reproductive technology. This title does not prohibit any activity that is authorized under Title I. | |
| Section 210<br><br>**Medical information that is not genetic information** | An employer, employment agency, labor organization, or joint labor-management committee shall not be considered to be in violation of this title based on the use, acquisition, or disclosure of medical information that is not genetic information about a manifested disease, disorder, or pathological condition, even if such has or may have a genetic basis. | The underlying genetic information that may have served as the basis for the manifested disease remains covered by the Act |
| Section 211<br><br>**Regulations** | Not later than one year after the date of enactment of this title, the EEOC shall issue final regulations to carry out this title. | Regulations must be issued by May 21, 2009 |
| Section 212<br><br>**Authorization of Appropriations** | There are authorized to be appropriated such sums as necessary to carry out this title (except Section 208 relating to the creation of a Commission to study disparate impact under this title). | |
| Section 213<br><br>**Effective Date** | This title takes effect eighteen months after the enactment of this Act. | This title takes effect on November 21, 2009 |

# Summary of EEOC Final Regulations on GINA Title II

EEOC Final Regulations on GINA Title II are codified at 29 C.F.R. Part 1635

## Key Definitions

The final regulations define employee to include not only current employees but also applicants and former employees. In addition, the regulations define family member to cover persons who are or who become related to an individual through marriage, birth, adoption or placement for adoption. Thus, even if an adopted child is not related genetically to a covered employee, GINA prohibits the acquisition of genetic information regarding the employee's adopted child.

The final regulations clarify definitions including what constitutes a genetic test under GINA and provide examples of tests for purposes of GINA that are considered and are not considered genetic tests. For instance, tests for infectious and communicable diseases, complete blood counts, cholesterol tests and liver-function tests are not considered genetic tests. Genetic tests include but are not limited to:

- Certain genetic tests that might determine whether individuals are genetically predisposed to breast cancer, colon cancer, or Huntington's Disease;
- Carrier screening to detect the risk of conditions such as cystic fibrosis, sickle cell anemia, spinal muscular atrophy, or fragile X syndrome in future offspring;
- Amniocentesis;
- Newborn screening;
- Preimplantation genetic diagnosis performed on embryos created using in vitro fertilization;
- Pharmocogenetic tests to predict how an individual might react to a drug or particular dosage of a drug;
- DNA testing to detect genetic markers associated with information about ancestry; and
- DNA testing that reveals family relationships such as paternity.

The regulations also clarify the definition of "manifested disease" so that individuals whose diagnosis was principally based on genetic information would remain protected by GINA and that individuals who had manifested a genetically based disease continued to have their genetic information protected.

## General Prohibitions

The final regulations take an expansive view on both the prohibitions on discrimination as well as collection of genetic information; providing strong and unambiguous definitions of key terms and clear examples.

For instance, the regulations make clear that an employer may violate GINA without a specific intent to acquire genetic information. Further, the regulations broadly interpret the term "request" to include:

- the searching of an individual's personal effects to obtain genetic information or
- the making of requests for information about an individual's current health status in a manner likely to result in obtaining genetic information.

GINA prohibits retaliation against individuals who complain about the acquisition, use or disclosure of their genetic information or the genetic information of their family members. The preamble to the final regulations recognizes a potential claim for harassment on the basis of genetic information. However, the regulations specifically note that GINA does not create a cause of action on the basis of disparate impact. GINA provides remedies consistent with Title VII for individuals whose genetic information (or the genetic information of their family members) was acquired, used or disclosed in violation of GINA.

The regulation's make clear that GINA's exception for commercially and publically available information does not apply to materials made available to the public, or to some portion of the public, on a restricted basis (i.e., when more than simple registration is required for access). The exception also does not apply to publicly available materials accessed with the intent of obtaining genetic information such as the conducting of Internet searches on an individual in a manner likely to result in the obtaining of genetic information.

## Inadvertent Disclosure and Safe-Harbor Language

GINA exempts employers from liability for "inadvertent" receipt of medical history or genetic information of an individual or his or her family members. For example, accidentally overhearing a conversation by an employee or generally inquiring "How are you?" regarding an employee's health qualifies as an inadvertent disclosure under the regulations. In addition, genetic information that may be received in connection with an employee's request for FMLA leave would not violate GINA.

The Regulations impose an affirmative duty on employers and other covered entities to prevent acquiring genetic information. Employers are required under GINA to affirmatively inform healthcare providers not to collect genetic information as part of a medical examination intended to determine an individual's ability or fitness for work. The final regulations include specific safe-harbor provision language to include on forms or questionnaires in which a lawful request for medical information is made. The purpose of the safe-harbor

language is to caution healthcare providers not to provide a company with genetic information.

If an employer receives any genetic information in response to a lawful request that contained the required safe-harbor language, the disclosure will be deemed inadvertent—and not a violation of GINA.

## Wellness Programs

GINA allows employers to obtain genetic information in connection with employer-sponsored health services or wellness programs, as long as any identifying genetic information is accessible only to the employee and the healthcare provider. Employers offering an employer-sponsored wellness program are required to obtain knowing, voluntary and written authorization that is written in a manner that the individual providing the genetic information is reasonably likely to understand, describes the information being requested, from whom it is being sought and the safeguards to protect against unlawful disclosure.

The final regulations allow for employers to offer financial incentives to encourage employee participation in a wellness program, but employers cannot offer financial incentives to employees to provide genetic information. The EEOC adopts the same standard it has adopted in Enforcement Guidance under the Americans with Disabilities Act (ADA): a wellness program is voluntary if it neither requires employees to participate nor penalizes employees for non-participation. Thus, if an employer is offering an incentive for employees to complete a health-risk assessment that includes questions concerning the employee's medical history (or the medical history of the employee's family members), the employer must identify such questions and indicate that the employee need not respond to them in order to receive the incentive.

## Confidentiality and Posting Requirements

Like the ADA, GINA requires employers to keep records containing genetic information on separate forms and in separate medical files and to treat them as confidential medical records. According to the Final Regulations, genetic information placed in an employee's personnel file before November 21, 2009 does not need to be removed from the file. However, the prohibitions against disclosing or using genetic information apply to all such information, regardless of when it was obtained.

The Final Regulations also provide that every covered entity "shall post and keep posted in conspicuous places upon its premises where notices to employees, applicants for employment, and members are customarily posted a notice to be prepared or approved by the Commission setting forth excerpts from or, summaries of, the pertinent provisions of this regulation and information pertinent to the filing of a complaint."