

Summary and Guidance regarding the Genetic Information Nondiscrimination Act of 2008 (GINA)

The Genetic Information Nondiscrimination Act of 2008 (GINA) is a Federal law that prohibits discrimination in **health coverage** and **employment** based on genetic information. GINA related to health coverage generally came into effect between May 22, 2009, and May 21, 2010, and the provisions related to employment came into effect on November 21, 2009.

Below is a summary of the guidance from Office of Human Research Protections (OHRP) Department of Health and Human Services (DHHS) in regards to GINA.

Definitions and Applicability

GINA defines **genetic information** as:

- 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.

Not genetic information: information about the sex or age of any individual.

GINA defines a **genetic test** as:

- An analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detect genotypes, mutations, or chromosomal changes.

Not genetic tests: Routine tests that do not detect genotypes, mutations, or chromosomal changes, such as complete blood counts, cholesterol tests, and liver enzyme tests, are not considered genetic tests under GINA. Also, under GINA, genetic tests do not include analyses of proteins or metabolites that are directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

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Exceptions to GINA for Health Coverage

GINA's provisions prohibiting discrimination in health coverage based on genetic information **do not extend to** life insurance, disability insurance, or long-term care insurance. For example:

- GINA does not make it illegal for a life insurance company to discriminate based on genetic information.
- GINA's provisions prohibiting discrimination by employers based on genetic information generally do not apply to employers with fewer than 15 employees.
- For health coverage provided by a health insurer to individuals, GINA does not prohibit the health insurer from determining eligibility or premium rates for an individual based on the manifestation of a disease or disorder in that individual.
- For employment-based health coverage provided by group health plans, GINA permits the overall premium rate for an employer to be increased because of the manifestation of a disease or disorder of an individual enrolled in the plan, but the manifested disease or disorder of one individual cannot be used as genetic information about other group members to further increase the premium.
- GINA also does not prohibit health insurers or health plan administrators from obtaining and using genetic test results in making payment determinations

Exception to GINA for Research by Health Insurers and Group Plans

The following information does not typically apply to the type of research that is conducted at the University of Kentucky (UK); however it does apply to collect genetic information on behalf of a group health plan or health insurers.

GINA includes a "research exception" to the general prohibition against health insurers or group health plans requesting that an individual undergo a genetic test. This exception allows health insurers and group health plans engaged in research **to request (but not require) that an individual undergo a genetic test**. One example of this would be if UK HMO wanted to conduct a research protocol to estimate its future expenses for a certain medical condition based on genetic information. The exception permits the request to be made **but imposes the following requirements:**

- The request must be made pursuant to research that complies with DHHS regulations at 45 CFR Part 46, or equivalent Federal regulations, and any applicable state or local laws for the protection of human subjects in research;
- There must be clear indication that participation is voluntary and that noncompliance has no effect on enrollment or premiums or contribution amounts;

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- No genetic information collected or acquired as part of the research may be used for underwriting purposes;
- The health insurer or group health plan must notify the Federal government in writing that it is conducting activities pursuant to this research exception and provide a description of the activities conducted; and
- The health insurer or group health plan must comply with any future conditions that the Federal government may require for activities conducted under this research exception.

IRB Review and Informed Consent in Studies Involving Genetic Information

When investigators develop, and IRBs review, consent processes and documents for genetic research, they must consider the protections provided by GINA, particularly with respect to the following elements of informed consent that are required to be provided to subjects [unless an IRB has approved an alteration or waiver of these requirements in accordance with the requirements of HHS regulations at 45 CFR 46.116(c) or (d)]:

- A description of any reasonably foreseeable risks or discomforts to the subjects (45 CFR 46.116(a)(2)); and
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (45 CFR 46.116(a)(5)).

Investigators and IRBs should be aware that the **protections provided by GINA are pertinent to genetic research that is conducted prior to the effective dates of GINA**. Protections extend to genetic information obtained as part of any research study regardless of when the research was conducted. Therefore, IRBs conducting initial or continuing review of genetic research should take into account the protections provided by GINA when assessing whether such research satisfies the criteria required for IRB approval of research referenced above.

For informed consent form template language, please see the Instruction page for the Medical IRB informed consent form under the section DNA Banking and Genetic Research (#12) which can be found on the ORI website under <http://www.research.uky.edu/ori/FormsHELP/S2C.htm>, or the Instruction page for the Nonmedical IRB informed consent form under the section DNA Banking and Genetic Research (#8), http://www.rgs.uky.edu/ori/FormsHELP/S2C_NM.htm.

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Reference: Office for Human Research Protections (OHRP) Department of Health and Human Services (HHS) "Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards (March 9, 2009).

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