What is GINA?

The Genetic Information Nondiscrimination Act, also referred to as GINA, is a federal law enacted in 2008. It provides a baseline level of protection against discrimination for all Americans in health coverage and employment on the basis of genetic information. GINA, together with already existing nondiscrimination provisions of the Health Insurance Portability and Accountability Act (see HIPAA guidance), generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or the individual’s family members, or using it for decisions regarding coverage, rates, or preexisting conditions. The law also prohibits most employers from using genetic information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment. GINA’s health coverage non-discrimination protections do not extend to life insurance, disability insurance and long-term care insurance. Further, GINA’s employment provisions do not apply to employers with fewer than 15 employees. For more information on GINA, go to http://www.genome.gov/24519851. (Accessed 9/10/11)

What is genetic research?

RowanSOM defines genetic research as research that involves the analysis of DNA, RNA, chromosomes, proteins, or certain metabolites which might act as or identify markers associated with a known or suspected predisposition to disease or behavior. Usually genetic research involves the collection of human biological material such as blood, skin or other tissues, nail clippings or hair. Genetic research also may include the construction of pedigrees (maps of the distribution of a particular trait or condition among related individuals or family medical histories). Although gene transfer is another form of genetic research, this guidance document does not apply to gene transfer research.

What is genetic information?

GINA defines genetic information as information about:

- An individual’s genetic tests (including genetic tests done as part of a research study);
- Genetic tests of the individual’s family members (defined as dependent 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 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 family member.

Genetic information does not include information about the sex or age of any individual.
What information about GINA should be communicated as part of the informed consent process to individuals participating in a research study with a genetic component?

Because breaches of privacy and confidentiality of genetic data may have potential economic harms on participants, whenever investigators develop consent processes and documents for research that include a genetic component, the following mandatory risks of economic harm language provided by GINA must appear in the consent document after the physical risks of harm section:

- Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others. Therefore, your genetic information potentially could be used in ways that could cause you or your family economic stress.
- There are state and federal laws that protect against genetic discrimination. A federal law, the Genetic Information Nondiscrimination Act makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: (1) health insurance companies and group health plans may not request your genetic information that we get from this research; (2) health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums; and (3) 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. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Updated 9/10/11