

Client Alert - GINA May Affect Informed Consent Forms

On May 21, 2008, the President signed into law The Genetic Information Nondiscrimination Act of 2008 (known as "GINA"), making it illegal for a health plan or insurer to deny coverage or charge higher premiums to a healthy person or their family based solely on genetic predisposition to a disease. GINA is intended to prohibit employment and health insurance discrimination on the basis of genetic information and provide individuals with protection against improper use of their genetic information. GINA amends certain laws, most notably The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the privacy laws promulgated under HIPAA. In doing so, GINA may create additional liabilities for institutions that conduct clinical research.

Under current (pre-GINA) law, some potential research subjects have been reluctant or unwilling to participate in genetic testing or genetic research for fear that their information could be used against them by employers or insurers. Now GINA prohibits insurers from 1) requesting or requiring genetic testing of an individual or his family or 2) using genetic information to determine eligibility or establish premiums. GINA also prohibits employers from 1) requesting or requiring genetic testing of an individual or his family or 2) using genetic information to make hiring or promotional decisions, or when determining eligibility for training programs. While GINA may lessen patient fears about genetic discrimination and thereby reduce patient concerns about participation in clinical research, GINA has the potential to hinder the advancement of genetic research.

Under HIPAA, the use and disclosure of certain "protected health information," generally referred to as "PHI," requires a valid consent from the research study subject. Generally, PHI means individually identifiable health information. Under GINA, "genetic information" is treated as "health information" for purposes of HIPAA, and health information is deemed PHI if a person can be individually identified by the "genetic information" in question. "Genetic information" under GINA means information about "genetic tests" of the individual or his/her "Family Member" (as defined by the act) and the manifestation of a disease or disorder in family members of such individual. If the "genetic information" is PHI and protected by HIPAA, a valid consent must be obtained from the research study subject for the use and disclosure of that "genetic information".

The term "genetic test" means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, which detect genotypes, mutations, or chromosomal changes. An important exception to the definition of "genetic test" under GINA is that "an analysis of proteins or metabolites that is 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" is not a genetic test.

Therefore, when a researcher runs any "genetic test" and the information from that "genetic test" can individually identify the research subject, such information would be considered PHI and would be protected under the rules of HIPAA. Any use or disclosure by a covered entity would require a HIPAA Authorization from the person so identified.

The Act requires the Secretary of Health and Human Services ("HHS") to issue by May 22, 2009 final regulations revising the privacy regulations so they are consistent with GINA. GINA has numerous ambiguities that HHS will need to address in subsequent guidance. For example, if the "genetic information" of a study subject could identify the child of a research study subject, would an authorization be required of the child as well? Most importantly, there is no clear indication as to when "genetic information" would be deemed to be identifiable.

GINA could have a very positive impact on clinical research involving the development of pharmacogenomics, or “personalized medicine”. Pharmacogenomics is the study of how genetic differences affect an individual's response to a drug. Pharmacogenomics also uses genetic information to determine a patient's risk of developing a disease and bases treatment on this information. GINA affords protection from this information being misused and putting patients at risk for genetic discrimination by insurers and employers. Alternatively, GINA may have a negative impact on research as it has the potential to create further confusion in the interpretation and administration of already complicated privacy laws.

Institutions should review clinical research protocols to determine if genetic information will be collected from research subjects, whether the genetic information will enable the study subject to be individually identified, and for what purposes such information will be used. In addition, institutions should ensure the applicable informed consent form adequately describes the permitted uses and disclosures of the genetic information.

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