Community Healthcare System

The Review

Community Healthcare System Central IRB (CHS CIRB)
Website: www.drcomhs.org

Volume 2 No. 7 **July 2019**

Who is GINA?

GINA is not a "who" but a "what". GINA is the acronym for the Genetic Information Nondiscrimination Act that was signed into law in May 2008. GINA specifically defines the term "genetic test" as the analysis of human genes, chromosomes, proteins, or metabolites to determine a person's genotype and whether the person has one or more gene mutations or chromosomal changes. Human genome research is creating new opportunities for a more individualized approach to the screening, diagnosis, and treatment of rare and common diseases. Genetic testing is also being used to determine whether and how a person will respond to a particular medication. Concerns about insurance discrimination, however, have led many people who could benefit from genetic testing, to choose not to have it. Others have chosen to pay for genetic testing on their own, because they feared they would be denied health insurance based on their genetic information if it were made available to their insurance carrier. As noted by Francis Collins, former head of the National Human Genome Research Institute: "This bill could just as well be known as the bill to protect people with DNA, and that would be all of us. Since each of us has dozens of genetic variations that may put us at risk for disease, we all would have had a reason to be concerned about the possible misuse of genetic information. With this act, Americans won't have to worry about their jobs or their health insurance being taken away because of the genes they inherited."

GINA does not allow the following behaviors:

1. Individual and group health insurers to use an individual's genetic information to determine whether they are eligible for health insurance;
2. An insurer to ask for or mandate that a person have genetic test;
3. Employers to use an individual's genetic information to make decisions about job
4. assignments, whether t hire or fire an individual, or any other terms of employment; or
5. Employers to ask for, require, or buy genetic information about an individual or his family members.

Why would GINA be important information to the IRB? With the advances in DNA testing, one can no longer assure that biospecimens can ever be de-identified in the true sense of the word. Many of the studies that are being reviewed by the CHS CIRB contain offers to the subject to participate in optional research in which the subject agrees to submit blood or tissue samples for future research. Much of this future research involves genomic research. There is also the advent of biorepositories; facilities that store biospecimens and data which can then be provided to research collaborators. Collaborators may include government, academia, industry for the use of drug development, clinically relevant research trials, publications and posters, and the implementation of future healthcare policies. The biorepositories would maintain the data and specimens over time and control access to and use of the information. With the passage of GINA, the IRB can be confident that the subjects will be adequately protected from any potential discrimination based on their genetic information. It is hoped that people will be less reluctant to participate in genetic and genomic research when they have been assured that their information is protected under the law.

CHS CIRB Contact Information
Jana L. Lacera, RN, MSA, CDM
Director, IRB/Bio-Ethics
901 MacArthur Blvd.
Munster, IN 46321
Phone: 219-836-6862 E-mail: jlacera@comhs.org