

Genetic Information Nondiscrimination Act

Also known as “GINA”, the Genetic Information Nondiscrimination Act of 2008 (P.L. 110–233, 122 Stat. 881), is a Federal law that prohibits discrimination in health coverage and employment based on genetic information. Health insurers are prohibited from denying coverage to an individual or charging a person higher premiums based on an individual’s genetic information. Employers may not refuse employment based on genetic information and prohibits them from collecting such data.

Because the Act provides a number of safeguards, there is an anticipation that more families will participate in genetic tests. The results of the tests will be added to the knowledge base to provide improved medical care in the future. The Department of Health and Human Services and NHGRI has provided a fact sheet for GINA which can be accessed by selecting the following link: <http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf>

Placebo–Controlled Trials

Placebo–controlled trials have been controversial since the first trial of its kind was conducted in 1931 for the treatment of tuberculosis. Because patients that are randomly assigned to receive placebo may be chosen to forego treatment, ethicists have argued that in some instances, participants in research are giving up their rights and welfare for the advancement of science. Paragraph 29 of the Declaration of Helsinki also brought about controversy regarding placebo–controlled trials and required a note of clarification to ensure that the use of placebo–controlled trials stating that “extreme care must be taken in making use of a placebo–controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. In addition there were some exceptions to this notation and specific circumstances

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were required to conduct placebo–controlled studies without proven therapy.

Federal regulations require that alternate therapies are to be presented to the participant in the research and outlined in the informed consent document. In addition, all risks and benefits of research participation are provided by the research staff and documented in the informed consent document. Although in some therapeutic scenarios, the use of placebo–controlled research may be fairly straightforward, there may be instances in which it is not. The most important consideration in developing placebo–controlled trials is to ensure that the patients will not be harmed during the study and that they are fully informed of their choices of therapy throughout their participation in the research.

OHRP Report on IRBs

Although the report focuses only on IRBs that are under the jurisdiction of OHRP, the report titled “Recent Compliance Oversight Determinations” provides a great overview of what NOT to do if you are an independent or institutional review board.

The information is compiled from the various determination letters that were sent out over the past few years.

This report provides details of IRB shortcomings from Initial and Continuing Review to IRB Documentation, Findings and Procedures that is available approximately every two to three years. For more information regarding this report, select the following website link:

<http://www.hhs.gov/ohrp/compliance/findings.html>