

Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards

OHRP has posted on its website a finalized guidance document entitled, "Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards." The guidance document provides OHRP's first formal guidance on this topic. The document, which is available on the OHRP website at <http://www.hhs.gov/ohrp/humansubjects/guidance/gina.html> and <http://www.hhs.gov/ohrp/humansubjects/guidance/gina.pdf>, is intended primarily for investigators who conduct, and institutional review boards (IRBs) that review, non-exempt human subjects research involving genetic testing or collection of genetic information. The guidance document provides background on protections provided by the Genetic Information Nondiscrimination Act of 2008 (GINA) and discusses some of the implications of GINA for investigators who conduct, and IRBs that review, genetic research, particularly with respect to the criteria for IRB approval of research and the requirements for obtaining informed consent under the Department of Health and Human Services regulations for the protection of human subjects (45 CFR part 46). The *Federal Register* notice announcing the availability of this new guidance document can be found at <http://edocket.access.gpo.gov/2009/E9-7782.htm> or <http://edocket.access.gpo.gov/2009/pdf/E9-7782.pdf>.