Informed Consent: Research Involving Genetic Information

PURPOSE

This policy defines the base requirements for research involving genetic information as it applies to the Genetic Information Nondiscrimination Act of 2008.

SCOPE

All BCOM agents and students involved in human subjects research.

RESPONSIBLE OFFICIAL(S)

Institutional Official for Research, Director of Research, IRB Members.

DEFINITIONS

Genetic Information Nondiscrimination Act of 2008 (GINA):

a federal law that protects individuals from genetic discrimination in health insurance and employment.

Genetic Information:

an individual's genetic tests (including genetic tests done as part of a research study); genetic tests of an individual's family members (defined as dependents 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 an individual's 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 an individual's family members.
Genetic information does not include information about the sex or age of any individual.

Genetic Test:

an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detect genotypes, mutations, or chromosomal changes. Routine tests that do not detect genotypes, mutations, or chromosomal changes, such as complete blood counts, cholesterol tests, and liver enzyme tests, are not considered genetic tests under GINA. Also, under GINA, genetic tests do not include analyses of proteins or metabolites that are directly related to a manifested disease, disorder, or pathological condition.

POLICY

Investigators and IRBs must ensure that descriptions of the reasonably foreseeable risks of genetic research, and any statements describing the extent to which confidentiality of records identifying the subject will be maintained, do not overstate the protections provided by GINA (45 CFR 46.116(a)).
When investigators develop, and IRBs review, consent processes and documents for genetic research, they should consider the protections provided by GINA, particularly with respect to the following elements of informed consent that must be provided to subjects:

- A description of any reasonably foreseeable risks or discomforts to the subjects (45 CFR 46.116(a)(2)); and
- A statement describing the extent, if any, to which confidentiality of all records, including genetic information, identifying the subject will be maintained.

APPROVAL PAGE

Approved by: _____
Robert J. Ketchum, Ph.D.
Associate Dean, Academic & Pre-Clinical Affairs
Authorized Institutional Official for Research
Burrell College of Osteopathic Medicine

APPROVED
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