Informed Consent: Research Involving Genetic Information	RSP.026.00
Effective Date	May 2016
Last Revision/Review	July 26, 2023

1. Purpose

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

Scope: All Burrell faculty, staff and students involved in human subjects research.

2. Related Policy/Authority

Genetic Information Nondiscrimination Act of 2008

45 CFR 46.116 General Requirements for Informed Consent

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

3. Faculty/Staff Responsibilities

Responsible Official(s): Authorized Institutional Official for Research, Director of Research, IRB Chairperson, IRB Members.

4. Definitions/Abbreviations

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.

5. Procedural Steps

5.1 **Background Information for GINA**

GINA provides a baseline level of protection against genetic discrimination for all Americans. Many states already have laws that protect against genetic discrimination in health insurance and employment situations. However, the degree of protection they provide varies widely, and while most provisions are less protective than GINA, some are more protective. All entities that are subject to GINA must, at a minimum, comply with all applicable GINA requirements, and may also need to comply with more protective State laws.

GINA defines *genetic information* as information about:

- 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.

5.2 **Guidance**: Given that GINA has implications regarding the actual or perceived risks of genetic research and an individual's willingness to participate in such research, investigators and IRBs should be aware of the protections provided by GINA as well as the limitations in the law's scope and effect. IRBs should consider the provisions of GINA when assessing whether genetic research satisfies the criteria required for IRB approval of research, particularly whether the risks are minimized and reasonable in relation to anticipated benefits and whether there are adequate provisions in place to protect the privacy of subjects and maintain the confidentiality of their data. GINA is also relevant to informed consent. When investigators develop, and IRBs review, consent processes and documents for genetic research, they should consider whether and how the protections provided by GINA should be reflected in the consent document's description of risks and provisions for assuring the confidentiality of the data.

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:

1. A description of any reasonably foreseeable risks or discomforts to the subjects (45 CFR 46.116(a)(2)); and

2. A statement describing the extent, if any, to which confidentiality of all records, including genetic information and biospecimens, identifying the subject will be maintained.

5.2 **IRB Responsibilities:** When reviewing proposed or ongoing genetic research, IRBs should consider the protections provided by GINA when determining whether the research satisfies the following criteria required for IRB approval of research:

1. Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and (ii) whenever appropriate, by using procedures which are already being performed on the subjects for diagnostic or treatment purposes (45 CFR 46.111(a)(1));
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result (45 CFR 46.111(a)(2)); and
3. When appropriate, there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data (45 CFR 46.111(a)(7)).

6. Reports/Charts/Forms/Attachments/Cross References

7. Maintenance

Reviewed annually by Office of Research

8. Signature

Approved by	8/9/2023
Assistant Dean for Research	Date

9. Distribution List

Internal/External

10. Revision History

Revision Date	Subsection #	Summary of Changes	New/Cancellation/ Replacement Procedure? (if applicable)	Approval Date
July 2023		This SOP was converted from an institutional policy original approved in May 2016.		8/9/2023