**** BILL NO. ****

INTRODUCED BY ****

BY REQUEST OF THE ****

A BILL FOR AN ACT ENTITLED: “AN ACT GENERALLY REVISING LAWS RELATED TO PRIVACY; AMENDING SECTIONS 30-14-2820, 30-23-102, AND 30-23-104, MCA; AND PROVIDING AN IMMEDIATE EFFECTIVE DATE.”

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

Section 1. Section 30-14-2820, MCA, is amended to read:

"**30-14-2820. Civil penalty injunction.** (1) A violation of this part is a violation of Title 30, chapter 14, parts 1 and 2.

(2) A person who violates the provisions of this part ~~following the 30-day period described in 30-14-2817(3)~~ is liable for a civil penalty in an amount not to exceed $7,500 for each violation.

(3) The attorney general may bring an action in the name of this state to:

(a) recover a civil penalty under this section;

(b) restrain or enjoin the person from violating this part; or

(c) recover the civil penalty and seek injunctive relief.

(4) The attorney general may recover reasonable attorney fees and other reasonable expenses incurred in investigating and bringing an action under this section.

(5) The attorney general shall deposit a civil penalty collected under this section in a special revenue account to the credit of the department pursuant to 30-14-143."

Section 2. Section 30-23-102, MCA, is amended to read:

"**30-23-102. Definitions.** As used in this part, unless the context clearly indicates otherwise, the following definitions apply:

(1) "Biological sample" means any human material known to contain DNA, including tissue, blood,

urine, or saliva.

(2) "Consumer" means an individual who is a resident of this state.

(3) "DNA" means deoxyribonucleic acid.

(4) "Entity" means a partnership, corporation, association, or public or private organization of any character that:

(a) offers consumer genetic testing or neurotechnology products or services directly to a consumer; or

(b) collects, uses, or analyzes genetic or neurotechnology data.

(5) "Express consent" means a consumer's affirmative response to a clear, meaningful, and prominent notice regarding the collection, use, or disclosure of genetic or neurotechnology data for a specific purpose.

(6) (a) "Genetic data" means any data, regardless of format, concerning a consumer's genetic characteristics.

(b) The term includes but is not limited to:

(i) raw sequence data that result from sequencing all or a portion of a consumer's extracted DNA;

(ii) genotypic and phenotypic information obtained from analyzing a consumer's raw sequence data; and

(iii) self-reported health information regarding a consumer's health conditions that the consumer provides to an entity that the entity:

(A) uses for scientific research or product development; and

(B) analyzes in connection with the consumer's raw sequence data.

(7) "Genetic testing" means:

(a) a laboratory test of a consumer's complete DNA, regions of DNA, chromosomes, genes, or gene products to determine the presence of genetic characteristics of a consumer; or

(b) an interpretation of a consumer's genetic data.

(8) "Governmental agency" means an executive, legislative, or judicial agency, department, board, commission, authority, institution, or instrumentality of the federal government or of a state or of a county, municipality, or other political subdivision of a state.

(9) "Neurotechnology" means devices capable of recording, interpreting, or altering the response of an individual's central or peripheral nervous system to its internal or external environment and includes mental augmentation, which means improving human cognition and behavior through direct recording or manipulation of neural activity by neurotechnology.

(10) (a) "Neurotechnology data" means information that is captured by neurotechnologies, is generated by measuring the activity of an individual's central or peripheral nervous systems, or is data associated with neural activity, which means the activity of neurons or glial cells in the central or peripheral nervous system, and that is not nonneural information.

(b) The term does not include nonneural information, which means information about the downstream physical effects of neural activity, including ~~by~~ but not limited to pupil dilation, motor activity, and breathing rate. The term also does not include data inferred from nonneural information.

(11) "Person" means an individual, partnership, corporation, association, business, business trust, or legal representative of an organization.

(12) "Processor" means a person that processes genetic or neurotechnology data on behalf of an entity pursuant to a contract between the entity and the processor that prohibits the processor from retaining, using, or disclosing the genetic or neurotechnology data, or any information regarding the identity of the consumer, including whether that consumer has solicited or received genetic testing, as applicable, for any purpose other than for the specific purpose of performing the services specified in the contract.

(13) "Third party" means a person other than the consumer, entity, or processor."

Section 3. Section 30-23-104, MCA, is amended to read:

"**30-23-104. Consumer genetic or neurotechnology data -- privacy notice -- consent -- access -- deletion -- destruction.** To safeguard the privacy, confidentiality, security, and integrity of a consumer's genetic or neurotechnology data, an entity shall:

(1) provide clear and complete information regarding the entity's policies and procedures for the collection, use, or disclosure of genetic or neurotechnology data by making available to a consumer:

(a) a high-level privacy policy overview that includes basic, essential information about the entity's collection, use, or disclosure of genetic or neurotechnology data; and

(b) a prominent, publicly available privacy notice that includes, at a minimum, information about the entity's data collection, consent, use, access, disclosure, transfer, security, and retention and deletion practices for genetic or neurotechnology data;

(2) obtain initial express consent from a consumer, parent, guardian, or power of attorney for the collection, use, or disclosure of the consumer's genetic or neurotechnology data that:

(a) clearly describes the entity's use of the genetic or neurotechnology data that the entity collects through the entity's genetic testing or neurotechnology product or service;

(b) specifies the categories of individuals within the entity that have access to test results; and

(c) specifies how the entity may share the genetic or neurotechnology data;

(3) if the entity engages in any of the following, obtain a consumer's:

(a) separate express consent for:

(i) the transfer or disclosure of the consumer's genetic or neurotechnology data or biological sample to any third party other than the entity's processors, including the name of the third party to which the consumer's genetic or neurotechnology data or biological sample will be transferred or disclosed with the consumer's express consent;

(ii) the use of genetic or neurotechnology data beyond the primary purpose of the entity's genetic testing or neurotechnology product or service and inherent contextual uses; or

(iii) the entity's retention of any biological sample provided by the consumer following the entity's completion of the initial testing service requested by the consumer;

(b) informed express consent for transfer or disclosure of the consumer's genetic or neurotechnology data to third party persons for:

(i) research purposes; or

(ii) research conducted under the control of the entity for the purpose of publication or generalizable knowledge; and

(c) express consent for:

(i) marketing to a consumer based on the consumer's genetic or neurotechnology data;

(ii) marketing by a third-party person to a consumer based on the consumer having ordered or purchased a genetic testing or neurotechnology product or service. Marketing does not include the provision of

customized content or offers on the websites or through the applications or services provided by the entity with the first-party relationship to the consumer; or

(iii) sale or other valuable consideration of the consumer's genetic or neurotechnology data.

(4) comply with the provisions of 44-6-104 requiring a valid legal process for disclosing genetic or neurotechnology data to law enforcement or any other government agency without a consumer's express consent;

(5) develop, implement, and maintain a comprehensive security program to protect a consumer's genetic or neurotechnology data against unauthorized access, use, or disclosure; and

(6) provide a process for a consumer to:

(a) access the consumer's genetic or neurotechnology data;

(b) delete the consumer's genetic or neurotechnology data;

(c) revoke any consent provided by the consumer; and

(d) request and obtain the destruction of the consumer's biological sample.

(7) The requirements of subsections (6)(a) through (6)(d) must be waived if:

(a) the entity obtains express and informed written consent from a consumer, parent, guardian, or power of attorney for participation in a clinical research trial, including the collection and use of any genetic or neurotechnology data, which at a minimum must:

(i) be in accordance with the good clinical practice guideline issued by the international council for harmonisation of technical requirements for pharmaceuticals for human use;

(ii) be obtained no sooner than 14 days from the initial biological sample collection if the biological sample is collected for a primary purpose unrelated to clinical research;

(iii) be obtained separately from any other items of consent;

(iv) be in writing on a form with text that is easily readable with size 12-point font or larger;

(v) include the entity's biological sample and data retention, sharing, and use policies;

(vi) include notice that after consent is given, there is no right to access, inspect, or require the destruction of any genetic or neural biological sample or neurotechnology data; and

(vii) include notice that after consent is given, whole genome sequencing of the individual's biological sample could occur and is permitted without further notice to the individual;

(b) the genetic or neural biological sample and data is utilized for clinical research purposes only.

(8) The requirements of subsection (6)(d) must be temporarily waived if:

(a) a laboratory is governed under 42 CFR 493.1105;

(b) the laboratory retains the biological sample for no more than 2 years or the shortest time allowed under law, whichever is less;

(c) the laboratory does not share, test, or conduct additional analysis or research on the biological sample while the sample is being held under the retention requirements set forth in 42 CFR 493.1105 prior to the requested destruction of the sample; and

(d) when a clinical laboratory is certified by the centers for medicare and medicaid services, when the retention of a patient's biological sample does not exceed the time needed for compliance with any quality standard or regulation issued pursuant to section 263(a) of the Public Health Service Act, 42 U.S.C. 263(a).

(9) The requirements of subsection (7) supersede all exceptions to, and waivers of, informed consent in the federal policy for the protection of human subjects under 45 CFR, part 46.

(10) Genetic or neurotechnology data and biometric samples of Montana residents collected in the state may not be stored within the territorial boundaries of any country currently sanctioned in any way by the United States office of foreign asset control or designated as a foreign adversary under 15 CFR 7.4(a). Genetic or neurotechnology data or biometric data of Montana residents collected in the state may only be transferred or stored outside the United States with the consent of the resident."

NEW SECTION. **Section 4. Effective date.** [This act] is effective on passage and approval.

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