

This is an official translation of Parliamentary Act No. 62
on Human Genetics Research enacted by the Faroese Parliament on 17 May 2005.
This translation has been prepared for the Ministry of Health and Social Services.
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Parliamentary Act No. 62 on Human Genetics Research, dated 17 May 2005
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Pursuant to ratification by the Faroese Parliament,
the Prime Minister hereby assents and promulgates this Act of Parliament:

Article 1
Scope and Definitions

Scope

§ 1. The purpose of this Act is:

1. to protect the rights of individuals in connection with Human Genetics Research;
2. to establish the parameters for and to encourage research in the Faroe Islands into human genetics so that such research may in the end:
 - a. advance competencies in the cure and prevention of disease;
 - b. advance competencies within the Faroese National Health Care System;
 - c. establish a consummate research environment in the Faroe Islands.

Definitions

§ 2. In this Act, the following terms are deemed to mean:

Human Genetics Research: This legislation encompasses only human genetics research that is linked to Faroese genealogical data.

Tissue Registry: A bio-bank that contains human tissue samples.

Diagnosis Registry: A registry of diagnoses that the National Health Care System has compiled.

Genealogy Registry: A registry of the hereditary relationships among the Faroese.

Tissue: Organic material, e.g. blood from individuals, either living or dead.

Health Information: Information that encompasses the health data of the Faroese, including, but not limited to, diagnosis, treatment, test results, and medical drug usage.

Anonymized: Certain data is deleted so that it is not possible to recognize a specific individual. This information includes, but is not limited to, name, occupation, address, birth date, date of death, place of birth, name of spouse and siblings and national identification number.

WHO Classification: The current International Classification of Diseases and Health Related Problems (ICD).

National Health Care System: National hospital system; private, municipality-based general practitioners; the national pharmacy and private dentists.

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- Responsible Clinician:** An authorized health care professional associated with the Faroese National Health Care System.
- The Responsible Clinician, for a given research project, has responsibility for the contact between an individual and the authorities. The Responsible Clinician has the responsibility to ensure that the data on individuals held in the registries of the National Human Genetics Resource Centre is correct. Communication with an individual participating in a research study shall only occur via the Responsible Clinician.
- Law on Personal Data:** Parliamentary Act No. 73 on the handling of personal information, dated 8 May 2001, as amended.
- Law on Patients' Rights:** Resolution No. 867, dated 30 September 2002, on the entry into force in the Faroe Islands of the Danish Law on Patients' Rights, as amended.
- Law on Scientific Ethics:** Resolution No. 862, dated 30 November 1999, on the entry into force in the Faroe Islands of the Danish Law on a scientific ethics committee system and the management of biomedical research projects, as amended.
- Faroese Scientific Ethics Committee:** The committee referenced in the Law on Scientific Ethics as the "Faroese Regional Committee" or "the central committee", to which research projects shall be submitted for its evaluation.

Article 2
National Human Genetics Resource Centre;
Exclusive Rights of the National Human Genetics Resource Centre;
Patients' Rights

National Human Genetics Resource Centre

- § 3. The Minister of Health and Social Services is authorized to establish an administrative institution under the Ministry of Health and Social Services to be known as the National Human Genetics Resource Centre, whose mandate shall be to organize, develop and administer a Tissue Registry, a Diagnosis Registry and a Genealogy Registry and to process applications for permission to study the information contained in said registries.
2. The National Human Genetics Resource Centre [NHGRC] has the authority to enter into agreements regarding the study of information contained in said registries.
3. The Minister of Health and Social Services shall stipulate further regulations governing what conditions should be contained in the agreements regarding research activities, including, but not limited to, development and advancement of research in the Faroe Islands, use of Faroese human resources, provision of goods and services from Faroese enterprises, payment for services provided by the NHGRC and for access to the information and tissue samples made available by the NHGRC, and a percentage of the potential income derived from the results of the research.
4. When the NHGRC negotiates a contract regarding human genetics research, the NHGRC shall ensure that the contract is governed by Faroese law and that the legal jurisdiction stipulated in the contract is that of the Faroe Islands and Denmark.

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5. The Minister of Health and Social Services is granted the authority to promulgate regulations and directives governing the administration of the NHGRC and the procedures, security, and finances related to the operation of the NHGRC.

Exclusive Rights of the National Human Genetics Resource Centre; Patients' Rights

§ 4. Human genetics research related to the human tissue of individuals registered in the Faroe Islands can only be conducted by those entities with which the NHGRC has entered into a contractual research agreement.

2. The NHGRC has the exclusive right to provide, store and manage tissue samples and diagnoses for purposes of human genetics research.

3. An individual who provides tissue samples to the NHGRC shall be deemed to be a patient subject to the law governing patients' rights.

4. Research contracts shall, in each instance, require that a Responsible Clinician be associated with the research project.

5. The NHGRC is authorized to enter into agreements with qualified individuals within the National Health Care System to undertake the clinical responsibilities related to a specific research project.

6. The Minister of Health and Social Services has the authority to promulgate further regulations regarding the agreements the NHGRC enters into with Responsible Clinicians.

7. A Responsible Clinician shall be financially independent of the research project to which he or she is associated and consequently shall be compensated by the NHGRC.

8. With regard to human genetics research agreements, the NHGRC shall ensure the absolute respect for an individual's dignity, personal identity and fundamental human rights without discrimination.

Article 3 Tissue Registry, Diagnosis Registry and Genealogy Registry

§ 5. As the foundation for the activities envisioned by this Act, the NHGRC is mandated to establish and manage a Tissue Registry, a Diagnosis Registry and a Genealogy Registry containing anonymized data that is accessible only by the NHGRC. In connection with the research agreements entered into by the NHGRC, the NHGRC is authorized to transmit the necessary tissue samples and personal data to a research project for study.

2. In the contractual agreements regarding human genetics research, the NHGRC shall ensure without exception that the personal data and the tissue samples supplied by the NHGRC are only used in connection with the agreed upon research project. Furthermore, the NHGRC shall ensure that, after use by the research project, the tissue samples are duly returned to the NHGRC or destroyed.

§ 6. The Tissue Registry, the Diagnosis Registry and the Genealogy Registry shall be so organized that the collection, storage, handling and use of the registries are totally protected and secure and are used only for their intended lawful purposes.

2. The Tissue Registry, the Diagnosis Registry and the Genealogy Registry shall be maintained only in the Faroe Islands and only contain data that is or could be relevant for human genetics research.

National Human Genetics Resource Centre Collection

§ 7. The NHGRC is authorized to provide tissue samples, diagnoses, and genealogical data on Faroese individuals who are deemed by the NHGRC to have or who could potentially have significance for genetics research. This authority shall be exercised consistent with and with due consideration of the legislation governing scientific ethics, personal data, and other relevant law. It is not necessary, however, to obtain the consents required pursuant to the law on personal data in order to effect the transfer of diagnoses from the National Health Care System or for the transfer of data from genealogical records to the NHGRC.

2. Pursuant to agreements with and compensation from the NHGRC, individuals within the National Health Care System and others shall collaborate to make available relevant tissue samples and diagnoses.

3. The collection of tissue samples from health care professionals within the National Health Care System shall be limited to the amount deemed necessary by the NHGRC to conduct scientific research.

4. The Responsible Clinician of a specific research project, which has been approved by the Faroese Scientific Ethics Committee and the NHGRC, has the right to obtain relevant health-related personal data from the National Health Care System. This right is granted with the intent that diagnoses, etc. may be verified.

5. The NHGRC shall procure the information required to generate the Genealogy Registry and shall in this connection have the authority to obtain relevant personal data registered in the National Registry of Persons, and the documents deposited with the National Archives, pursuant to agreement and remuneration.

Registry Content

§ 8. The Diagnosis Registry shall contain only that health-related information referenced by the International Classification of Diseases and Health Related Problems plus data acquired directly from the analysis of a tissue sample.

The Tissue Registry shall store tissue samples.

The Genealogy Registry shall contain information regarding Faroese genealogy.

Usage

§ 9. Access to the NHGRC for use of the registries is conditioned on the NHGRC, together with a human genetics research enterprise, having previously obtained approval of a research project from the Faroese Scientific Ethics Committee and having obtained informed consents pursuant to the Law on Patients' Rights.

2. The provisions of paragraph 1 notwithstanding, the NHGRC shall have access to the Diagnosis Registry and the Genealogy Registry with regard to the provision of data for health-related reporting and other statistical purposes. In addition, the NHGRC is granted access to the Diagnosis Registry and the Genealogy Registry to facilitate preparatory work related to the negotiation and drafting of human genetics research agreements.

§ 10. Testing that may detect hereditary disease or that either may identify an individual as a bearer of a genetic trait that is deemed a precursor to a disease or may reveal a genetic trait that might predispose an individual to a disease shall only be conducted in the interest of promoting the health of the individual or for health-related purposes and shall be conditioned on the provision of relevant and appropriate genetic counselling.

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2. Any and all discrimination directed at an individual based on an hereditary genetic trait or condition is strictly forbidden.

Assignment / Legal Proceedings

§ 11. Tissue samples or data contained in the Tissue Registry, or the Diagnosis Registry or the Genealogy Registry may not be conveyed or assigned as property or collateral, either wholly or partially, and the tissue samples or the data, etc. shall not be subject to attachment or lien.

Article 4 Penalties

§ 12. Violation of this Act or of the regulations promulgated under authority of this Act shall be punishable by a fine or imprisonment of up to three (3) years, unless stronger punishment is authorized pursuant to other legislation.

2. Companies, etc. (juridical persons) may be subject to the penalties herein pursuant to the provisions of Article 5 of the penal code.

3. For violation of § 4 above, all tissue samples and all information related to diagnoses may be seized and impounded.

Article 5 Entry into Force

§ 13. This law shall enter into force the day after it is promulgated.

Tórshavn, 17 May 2005

/signature/
Jóannes Eidesgaard
Prime Minister

/Signature/
Hans Pauli Strøm
Minister of Health and Social Services

Bill No. 83/2004