Chapter 1. General Comments

Purpose of the legislative proposal, etc.
Genetics research is principally related to:

1. quicker diagnosis and thus faster treatment
2. the development of medicinal drugs
3. treatment with reduced side effects
4. better delivery of health services.

Why this law on genetics research?
The resources being studied are not like other natural resources. In this instance, individual human tissue is obtained and studied for evidence of possible serious diseases. The area covered by this legislation is genetics research associated with genealogical data and only this area is regulated because this type of research is deemed to be especially sensitive and fraught with emotional concerns.

With regard to this type of research, it is deemed appropriate that for each research program a person associated with the Faroese national health care system shall be required to serve as a point of contact between the individual to be studied and the researcher. This contact person shall 1) inform the individual about the nature of the research to be conducted, 2) ascertain whether the individual, after being properly informed, desires to be included in the study, and 3) also determine whether the individual and his /her relations manifest the specific disease under study. This condition in the legislation regarding a "Responsible Clinician" within the national health care system is stipulated in order to ensure the protection of an individual's dignity and human rights and is a very advisable provision in the legislation.

An indispensable resource in genetics research that is grounded in genealogical records is that of the diagnostic data found in patient records, a resource that has long been present in the Faroese national health care system. Patient data have been maintained for many years, diligently recorded and stored by physicians and others for as long as the Faroese community has funded a national health care system. It is deemed reasonable and sensible, therefore, to provide for remuneration to the national health care system in the event that this resource shall be used in connection with a research study that has a potential for financial gain. This is done in an attempt to strengthen the national health care system and to ensure an income stream for on-going operations.

The Faroe Islands is well suited for genetics research. The inhabitants possess an homogenous ancestry in that the Faroese people, to a large degree, are descended from a limited number of early settlers in the 800s.

Since that time, the population has grown without any major influx from abroad. Furthermore, the genealogy of the Faroese, in comparison to other countries, is relatively well-documented for several hundred years because church records, cadastre and other written sources are available.

In addition, the registration over time of diseases and of patients has been good. For these reasons, it is quite probable that the Faroe Islands will be of interest, both with regard to public research organizations and private entities involved with genetics research grounded in genealogical data.

The purpose of this legislation is make the genealogical resources of the Faroese accessible to researchers in such manner that an individual can feel confident and fully protected regarding such research. The purpose of the legislation as well is to ensure that both the Faroe Islands as a whole and the individual researchers derive the most benefit from the various available resources.

By promoting research into the genetic basis for disease and disability, the Faroe Islands and the Faroese could very well assist humanity to gain insight into the dreaded diseases that plague many people around the world.

Genetics research in the Faroe Islands can have a dramatic impact on both the national health care system and other research in the Faroe Islands, including computer science, statistics, and the medical sciences, not to mention, of course, the significant impact on veterinary medicine and fish veterinary science, biology and other similar scientific areas of study. The result of these scientific endeavors could very well be expected to diversify the economy and as a consequence be of financial significance for the Faroese community.

Overall, the legislation creates a National Human Genetics Resource Centre [NHGRC] that shall organize, develop and administer the Tissue Registry, the Diagnosis Registry and the Genealogy Registry and process the applications for permission to conduct research utilizing the registries. The intent is that the NHGRC shall consolidate and digitize the registries so that they are accessible and thus ensure that some portion of the benefit to be derived from genetics research will transfer to the Faroese community as a whole. Regarding questions of ethics and the preservation of personal data, the Act places all research-related initiatives under the oversight of the Faroese Scientific Ethics Committee and the Faroese Data Protection Board.

In order for the NHGRC to begin its activities, it is necessary that the Genealogy Registry be expanded so that it is complete and comprehensive, in the first instance for a specific time period. When the Tissue Registry and the Diagnosis Registry will be completed is dependent on appropriations and the extent to which the governmental authorities will prioritize work on the registries.

Legislation Now in Force

One important aspect of the work on this Act has been to ensure that the legislation is not in conflict with current juridical provisions within the various areas relevant to the legislation and that the Act totally falls within the protections afforded by other legislation. First and foremost, attention was paid to the law on scientific ethics and the law governing personal information.

Furthermore, attention was directed to ensuring that the proposed legislation was not only in compliance with current law and regulations in the Faroe Islands, but also consistent with international conventions, even though these conventions might not yet be ratified and in full force and effect in the Faroe Islands.

The jurisprudence in effect in the Faroe Islands and that is relevant for purposes of this proposed legislation is:

1. the Home Rule Act;
2. Danish Act No. 316, dated 17 May 1995, on the health care system in the Faroe Islands;
3. Faroese Parliamentary Act No. 89, dated 4 June 1996, on the Faroese Hospital System;
4. Faroese Parliamentary Act No. 73, dated 8 May 2001, on the handling of personal information (the Law on Personal Information);
5. the Law on Scientific Ethics (Resolution No. 862, dated 30 November 1999 on the scientific ethics committee system and the administration of bio-medical research projects);
6. the Convention for the Protection of Human Rights and Fundamental Freedoms;
7. Resolution No. 827, dated 30 September 2002, on the entry into force in the Faroe Islands of the law on patients' rights.

Other jurisprudence considered includes:

1. the Convention on Human Rights and Bio-medicine, Oveido, 4 April 1997. (Notice of the European Commission's convention dated 4 April 1997 on human rights and bio-medicine;
2. Recommendation No. R (97) 5 of the Committee of Ministers to the member states on the protection of medical data (Council of Europe);
3. World Medical Association Declaration of Helsinki (Ethical Principles for Medical Research Involving Human Subjects);
4. Law on Patients' Rights (LBK No. 272 dated 19 April 2001).

Section 4, paragraph 8 stipulates the parameters for all genetics research in the Faroe Islands. The provision is based on international human rights agreements, including the Human Rights Convention as well as other conventions referenced above.

With regard to its activities, the NHGRC shall, therefore, extend the greatest respect for an individual's dignity, personal identity and fundamental human rights without discrimination as set forth in § 4, paragraph 8 of the Act.

The Home Rule Act does not contain any provision that contravenes this legislation.

Concurrently, it is noted that the law on the national hospital system grants the Faroese Parliament the authority to promulgate legislation within this juridical area.

Some Comments on Genetics Research

Human genetics research, which this law is intended to administer and permit, is focused on the determination of where in the human DNA sequence are the genes responsible for specific diseases or dysfunction in the body.

Today, it is possible with advanced technology to investigate the entire human DNA sequence. This is a very recent phenomenon, as the technology has only been available for the last few years. This has meant that efforts are underway worldwide to isolate where within the human DNA sequencing reside the cause or causes for diseases.

This research is conducted to ascertain how the human body functions, especially with the hope that new and more effective drugs against disease or dysfunction could be produced based on this knowledge.

The human body is composed of tiny cells. Each cell contains a nucleus wherein are found 23 pairs of chromosomes. Half of the chromosomes come from the father and half from the mother.

A gene is a part of a chromosome, which is responsible for one hereditary trait in the body. Within a chromosome are long double strands referred to as "DNA". This strand of hereditary material can be compared to a long continuous text that is comprised of only four letters. The four letters refer to four chemical compounds or bases, which are generally referred to as A, T, G and C. The sequencing of these bases determines how certain amino acids will be linked together to form various proteins. The proteins subsequently determine how the cell functions. The cells orchestrate the functioning of the body.

Research can be conducted in a variety of ways. One method is based on the knowledge contained in genealogical records. The Faroe Islands finds itself in the favorable position that it is quite suitable for this type of research, because we have been so isolated through the centuries. This means that most Faroese are in one way or another all related.

The approximately five thousand people who lived here 200 or 300 years ago have now increased some 10 times, but their heritage is the same. This means that in the Faroe Islands, as in Iceland, there are excellent possibilities to conduct research studies. Other isolated societies have equally good circumstances, but difficulties may arise in that their health care system has not had and / or does not have a good understanding of what diseases afflict its people, or, in other words, their diagnoses are not so well documented.

Historical Overview

Genetics research is not an especially new phenomenon. Mankind has long observed the hereditary characteristics of people, animals and plants.

It was George Mendel, who in the middle of the 19th century, laid the underpinnings of scientific genetics research with his study of how plants transfer hereditary characteristics.

In *1900*, Landsteiner classified blood into the groups A, B and O and in 1911 demonstrated that these blood groups were transmitted according to the patterns articulated by Mendel.

In *1902*, Sutton and Boveri, discovered that it was the chromosomes (the core strands in the cell nucleus) that carried hereditary characteristics.

In *1944*, Avery and his colleagues published their findings that hereditary transfer was based on a protein structure generally referred to as DNA, which stands for deoxyribonucleic acid.

In *1953*, Watson and Crick discovered that DNA is a double helix strand composed of four bases. Subsequent to this discovery, genomic studies rapidly progressed.

The largest research project to date within genomic studies is the so-called HUGO project (the Human Genome Project) that began in 1990 and was completed in 2001. This project was initiated in the United States and the principal purpose was to map the entire human gene sequence and to make this information available to all so that anyone with an interest could use the data. The project determined that humans have around 30,000 genes.

Legislative History and Comments

The proposed legislation has been through the hearing process with the Faroese Personal Data Board, the Faroese Scientific Ethics Committee, the Faroese Police Commissioner, the Office of the Danish Representative on the Faroe Islands, the national hospital in Tórshavn, the hospital in Klaksvík, the hospital in Suðuroy, the national pharmacy, the Faroese Research Council, the University of the Faroe Islands, the Office of the Prime Minister, the Ministry of the Interior, the department of culture in the Ministry of Culture, the department of commerce in the Ministry of Trade and Industry, the Ministry of Finance, the Ministry of Fisheries and Maritime Affairs, the national archives, the Faroese diocese of the Lutheran Church, the Faroese exchequer, the Faroese Medical Association, the Faroese Municipal Physicians Association, the Association of Young Physicians, the Faroese Nurses Association, the Association for the Disabled, the Diabetes Association, and the House of Industry.

The Ministry of Health and Social Services has received 19 comments from the various hearings. A collection of these responses (in Faroese) is available digitally. The recommendations in the responses have been duly noted and adopted to the extent possible.

Article 2 Consequences of the proposed legislation

Fiscal consequences for the country and the municipalities
The proposed legislation has a financial impact on the country.

Notable Initial Costs
It will be necessary to organize the **Genealogy Registry** in such a manner that the genealogy registries are digitized, in the first instance from the year 1800 to the present. This work is estimated to take around three years with staff that are familiar with history, genealogical study and computers. In addition, it will necessary to purchase the requisite software for this work. Estimated costs to produce the Genealogy Registry are approximately three million DKK. The Genealogy Registry must be completed before the National Human Genetics Resource Centre can offer concessions to engage in specific human genetics research projects. The intent, however, is to begin initially to digitize the genealogical registries from the 19th and 20th centuries.

The other principal area is to ensure that the **Diagnosis Registry** is updated, reviewed to ensure quality control and managed in such manner as to ensure that the information is correct and useful, especially for research purposes. Estimated expenses related to this work are around one million DKK. The Diagnosis Registry can be compiled and digitized as funds are made available or are obligated.

Procurement of the necessary equipment resources to create an anonymized and secure **Tissue Registry** is mandated. In addition, laboratory equipment to extract the DNA from tissue samples so that only the least amount of tissue material is provided each individual research project. The estimated costs for this equipment is approximately one million DKK. The Tissue Registry, as the Diagnosis Registry, can be compiled and digitized as funds are made available or are obligated.

It will be necessary to **encrypt** the personal data in the Diagnosis Registry, the Genealogy Registry and Tissue Registry, so that the same individual receives the same encryption code in each of the three registries. Without this, it will impossible to compare the data in the registries. This data encryption shall take place outside of the NHGRC. The estimated costs associated with the initial encryption efforts are approximately 0.5 million DKK. Subsequently, these costs will be borne by each individual research project.

Of course, the **NHGRC itself** will require expenditures for wages and office expenses. The intent is that a core of full-time staff would ensure on-going operations, while many services will be outsourced as necessary, e.g. legal, accounting, statistical, etc. It is estimated that annual costs would be approximately three million DKK.

Altogether, expenses would run about 8.5 million DKK and this is deemed to be the minimal amount necessary in order to initiate the concept. After about one year, when the necessary registries are in place, the intent is that the activities of the NHGRC shall be financed from income from the research projects that are anticipated to be initiated. Thus, the intent is that the NHGRC, once the research projects begin to generate income, shall not require funding from the national treasury, but only financed by the income from corporate research entities and public research initiatives.

The proposed legislation will have an impact as well on the national health care system in that various responsibilities will be imposed on the national health care system. For example, the national health care system will be required to compile and maintain a patient registry, tissue samples and medicinal drug information in accordance with specific directives and compensation agreements. In the first instance, this compensation shall be paid by the NHGRC, but subsequent expenses will be borne by the corporate research entities that have entered into agreements with the NHGRC. Payment to the national health care system could very well be arranged so that a department within the national health care system could receive the funds from the NHGRC for the purpose of hiring extra staff, for a limited time, or allocated to one staff member who would take full-time responsibility for this area as the Responsible Clinician. In short, the department would receive extra funds to take on the additional responsibilities so that normal operations are not unduly prejudiced.

In addition, the National Registry of Persons and the National Archives are responsible to provide the Human Genome Repository, pursuant to relevant agreements and compensation, the information that shall form part of the underlying basis of the Genealogy Registry. The intent is that the compensation for 2005 would be paid from the national budget, but prospectively the maintenance, expansion and development of the Genealogy Registry will be paid for via the research projects.

Comments regarding income
As stated above, there are many who would seize the opportunity to conduct research in specific diseases that are found within the Faroese cohort.

Several inquires have been received by the Ministry of Health and Social Services for access to this resource.

It is difficult to measure the amount of income that the NHGRC could receive during the coming years, because in the beginning it must establish the groundwork for research, namely the Tissue Registry, the Diagnosis Registry and the Genealogy Registry of the Faroese.

It is evident, however, that sooner or latter, the NHGRC will enter into a research contract that will realize financial gain.

It is not unreasonable to assume that research entities could be required to conduct some of their work here in the Faroe Islands and thus leave a contribution to society, including, but not limited to payment of local taxes.

Further, it is reasonable to assume that there will be a need to purchase local goods and services, which would again contribute income to the national treasury.

Human genetics research will as well have major importance for other research conducted in the Faroe Islands. Fish veterinary research, especially in the areas of disease prevention and cross-breeding within the aquaculture industry, could well gain much from this type of research and this will in turn increase the flow of revenue to the national treasury.

Administrative consequences for the country and the municipalities
It will be necessary to administer the NHGRC and consequently there will be administrative consequences and responsibilities that will fall upon the national health care system.

Other Consequences
It is felt that the proposed legislation will not have any social or environmental impacts nor contravene any international agreements or conventions.

Overview of Consequences

Consequences	For the country/ national authorities	For the municipalities	For national land sectors / regions	For specific community interests	For business and commerce
Financial / Budgetary	Yes	No	No	No	Yes
Administrative	Yes	No	No	No	No
International agreements / International conventions	No	No	No	No	No
Social				No	

Chapter 3. Special Annotations

To § 1
This section presents the scope and purpose of the legislation. The article address two central themes, which are prioritized in such manner as the most important is placed first, namely that of the protection of the individual. In short, these two themes can be summarized thus:

Protection
As stated in the general comments, there is a principal in most countries that research is independent of any specific legal restraint that would limit or curtail its purview.

At present, for the most part, there are no limitations on the right of free and independent research, except that regarding human biological research. In this regard, permission to conduct research is required from the Faroese Scientific Ethics Committee and the Faroese Data Protection Board. It is believed that the protection of an individual's rights must be strengthened so that security is of such a high degree as possible, including, but not limited to, to the requirement that research is conducted with only anonymized information.

Prerequisites
It is well understood that genetics research is especially demanding, both with regard to the financial resources required and, of course, the level of research-related competencies. In addition, considerable trust and goodwill is demanded of those who, in one way or another, are asked to take part in this type of research. The research shall, therefore, be conducted in such manner that all will feel assured that their personal information is securely protected.

In order to establish the requisite conditions under which to conduct genetics research, a centralized, coordinating agency will be created, under the aegis of the national health care system, to be known as the National Human Genetics Resource Centre, which would enter into well-crafted and strict agreements with interested and well-qualified research institutes or entities, who would, for example, conduct research based on the information provided in the registries.

Genetics research demands specialized knowledge and competency of the highest caliber, with regard to not only biological expertise, but also with regard to computer science, statistics, medicine and other scientific disciplines. The Faroe Islands at present has but little expertise in these areas. The intent, therefore, to the extent possible, is to require that the research be conducted in the Faroe Islands and thereby develop the level of relevant competencies in the Faroe Islands and ensure commercial development.

To § 2
To avoid repetitive explanations and to make the legal text more concise and easier to read, several terms used throughout the text are defined.

To § 3
To paragraph 1
The Minister of Health and Social Services does not need enabling legislation to establish a public agency or office, notwithstanding that for similar areas of interest, e.g. security issues, it would be normal that the Parliament from the beginning would determine the framework for a public agency, as in the case of the law governing the establishment of the Post and Telecommunications Surveillance Authority. The result is that when the law is ratified the mandate for the agency that shall administer the law is promulgated.

The principal purpose of the National Human Genetics Resource Centre is to create the various registries that are the very prerequisites for genetics research.

The mandate of the law is so constructed that the time period and the fiscal implications are not specified. It is deemed that these aspects are political in nature and thus the extent of financial support initially budgeted and the scope of the various registries and the speed with which they are compiled and made available are political decisions. It goes without saying that the sooner the Genealogy Registry is available, the sooner relevant research projects could get underway.

The intent is that the NHGRC would have a manager and limited administrative staffing, but that all other services would be outsourced. This type of organization is based on the fact that very complex and abstruse science is involved that generally is only administered by individuals with specialized knowledge in the area. At present, the concept is that the Genealogy Registry would be compiled by individuals knowledgeable in the area of genetics-related registries and the relevant issues involved. Thus, according to the intended model, there would be few employees of the NHGRC, but rather services would be procured as the need arose. Further, temporary employees could be used.

To paragraph 2
As stated above under the general comments, genetics research is, for the most part, pursued by the major pharmaceutical companies and research enterprises.

To compile and develop the registries of the NHGRC will require the expenditure of considerable sums. Therefore, a fundamental precondition is that interested researchers should compensate for access to the information they desire to study. This means that the NHGRC should set forth as a stipulation in any contract for services that a specific amount shall be paid to the Resource Centre for research access to the information maintained by the Resource Centre. In this context, the stipulation should be such that the remuneration requested shall include not only an advance fee designed to assist in the development and maintenance of the registries, but also a percentage of the financial income or gain that might be derived from the exploitation of the results of the research, a so-called royalty payment. Among the expenses for which the NHGRC, pursuant to the intended model of operation, shall request payment for would be a fee for the Responsible Clinician, to whom the NHGRC provides compensation, confer § 4, paragraph 7 and specific comments.

This means that comprehensive agreements that include certain legal, fiscal and scientific provisions shall be negotiated in each instance and crafted in such manner as to protect the interests of the NHGRC. The specific interests of the NHGRC are focused on ensuring its solvency, compensation to the national health care system and the National Archives, the advancement of research in the Faroe Islands to the greatest extent possible and the development of the Faroese national health care system, as well as potential royalty income.

To paragraph 3
There is considerable difference between the legal system of the Nordic countries and that of other countries. This can lead to disagreement as to what legal jurisdiction is relevant. Thus, it has been determined that all the agreements entered into by the NHGRC shall be drafted consistent with and governed by Faroese law. As a further protection, it shall be stipulated that the courts of competent jurisdiction shall be that of the Faroe Islands and Denmark.

To paragraph 4
Authority is granted to the Minister of Health and Social Services to promulgate specific regulations governing the establishment of the NHGRC consistent with relevant governmental procedures. It is advisable at the same time to grant authorization to promulgate regulations governing the administration of the NHGRC as well as security and fiscal issues and the daily management of the NHGRC.

The possibility to promulgate regulations on security is advisable in order to establish procedures that would comply with the requirements set forth by the Faroese Data Protection Board regarding physical security arrangements, secure copies as well as a variety of other related issues. In addition,

authority is provided for the promulgation of regulations governing the administrative transparency of the NHGRC so that there is no doubt regarding any potential conflicts of interest.

To § 4

To paragraph 1

This provision stipulates that, in order to conduct research on tissue of individuals registered with the NHGRC, a contract must be in place with the NHGRC. By individuals registered in the Faroe Islands is meant those individuals who are registered as residing in the Faroe Islands when a specific research project is deemed up and running, including those who have been registered as living in the Faroe Islands, but reside abroad.

To paragraph 2

This provision stipulates that the NHGRC has the exclusive right to provide the data that is the basis for genetics research. In order to achieve the purpose of establishing the NHGRC, which is a publicly administered agency for genetics research into the data found within the national health care system, it is necessary that this information not be housed by any entity other than the NHGRC. This is to ensure that the NHGRC can be an attractive collaborator for researchers.

If the NHGRC does not have the exclusive right to house and administer the various registries, then the exclusive right to enter into contracts with genetics researchers has no value.

Furthermore, it could be prejudicial to the interests of the country if a foreign enterprise went directly to an individual and subsequently obtained his or her information from the national health care system, even though the Faroese Scientific Ethics Committee otherwise had approved the research project and the Faroese Data Protection Board had granted permission to obtain such data.

The exclusive right is drafted in such a manner as not to, obviously, impact on the normal collection of blood, whether related to blood banking or screening, disease diagnosis or treatment.

To paragraph 3

In order to fully protect an individual who submits tissue samples for a specific project, said individual is deemed to be a "patient" with all the attendant rights and privileges accorded thereto. This is an extra assurance designed to protect individuals.

To paragraph 4 and 5

Pursuant to stipulations in the law on scientific ethics, it is a requirement that a "Responsible Clinician" be assigned to collaborate with each research study. In this legislation, there is an additional requirement that the Responsible Clinician is an individual that works within the Faroese national health care system. The national health care system, pursuant with this law, encompasses the national hospital system, the municipal physicians, the national pharmacy, dentists and privately employed health care professionals. The NHGRC thus has many options to locate a suitable Responsible Clinician. A Responsible Clinician is associated with each individual study and does not need to be the same individual from project to project.

The respective Responsible Clinician shall serve as the liaison between the NHGRC and those who donate their tissue samples for study. Moreover, the respective Responsible Clinician shall bear the responsibility of reviewing the accuracy of the information obtained from the various sectors of the national health care system before this information is anonymized and transferred to the NHGRC and subsequently shared with the respective researchers.

In the event that the national health care system is not able to voluntarily provide a Responsible Clinician, the NHGRC is hereby given the authority to appoint a qualified individual from within the national health care system, pursuant to a specific negotiated agreement with the national health care system.

To paragraph 6
The Minister of Health and Social Services is granted authority to promulgate specific regulations governing the agreements that the NHGRC enters into with the Responsible Clinicians. This authorization encompasses as well the stipulation of relevant requirements regarding the Responsible Clinicians. The following issues should be addressed in such regulations: the specific qualifications of the Responsible Clinicians, how the Responsible Clinicians should be selected, and what actions are necessary if the NHGRC determines that a Responsible Clinician is not suitable.

To paragraph 7
This provision stipulates that the Responsible Clinician shall be paid from funds of the NHGRC and shall not be associated with any research project in such a way as to have a financial stake in the study itself. This stipulation is designed to ensure that the Responsible Clinician assumes the role intended. The Responsible Clinician shall ensure that the information provided is correct and that contact with an individual patient is conducted appropriately. The Responsible Clinician shall therefore obtain the necessary consents consistent with Faroese law and ensure that the patient rights of the individual are protected. For these reasons, it has been decided that the Responsible Clinician shall not have any personal financial interests in the study being supervised. If an individual has a financial interest in a specific project, this fact could cast doubt on one's suitability, neutrality, etc.

To paragraph 8
Great emphasis is placed on the necessity that genetics research respects the fundamental human rights of all. These rights are set forth in international conventions.

Some of these conventions have been ratified by the Faroese Parliament, others have not. However, measures have been taken to follow the international protocols even though these may not be in force in the Faroe Islands. In the approval protocol of the Faroese Scientific Ethics Committee, for which the Committee has responsibility, it states that only scientifically ethical research projects will be approved. In addition, the requirements of the personal data law that are administered by the Faroese Data Protection Board are relevant.

To § 5
The principal purpose of the NHGRC is to establish and administer the Tissue Registry, the Diagnosis Registry and the Genealogy Registry. The intent is to organize and administer the registries in accordance with the directives and requirements stipulated by the Faroese Personal Data Protection Board in order to comply with the personal data protection law. The provisions in the personal data protection law stipulate strict conditions to safeguard an individual's personal information.

Common to all of the registries maintained by the NHGRC is that an individual's personal data is anonymized. This means that, before personal information is transferred to the NHGRC, the data is anonymized pursuant to the requirements established by the Faroese Data Protection Board. Anonymized encryption is defined in § 2.

The purpose for establishing and administering the registries is to enable the researchers with negotiated agreements access to the tissue samples and the information contained in the various registries.

To § 6
To paragraph 1
In addition to the security provided by anonymization as referenced in the comments to § 5 above, this section stipulates various general conditions: that the registries of the NHGRC shall be absolutely secure and that the registries shall only be used for lawful purposes. Essentially, the provisions ensure compliance with the legislation related to the protection of personal data, administrative rights and penalties, etc.

To paragraph 2
As an extra measure of security, it is stipulated that the Tissue Registry, the Diagnosis Registry and the Genealogy Registry shall be maintained in the Faroe Islands so that the governmental authorities here in the Faroe Islands always have complete supervisory and administrative control over the registries. When a portion of the research is required to be performed outside of the Faroe Islands – yet pursuant to the agreement with the NHGRC – it will of course be necessary for the NHGRC to provide the foreign researchers with anonymized health data. The same is true regarding tissue samples, but in the case of tissue samples the tissue itself is not transferred out of the Faroe Islands but only an extract of the tissue. With regard to the transfer of personal data out of the country, the requirements set forth in the legislation regarding the protection of personal information are relevant and shall be observed.

It is also stated that the registries administered by the NHGRC may only contain information that is relevant to genetics research. In this provision, the requirements regarding the handling of personal information stipulated in the law on the protection of personal information are made a part of the Act. For example, personal data (marital status, occupation, etc.), financial information and religious affiliation shall not be stored in the registries.

To § 7
To paragraph 1 & 2
The law on the protection of personal information requires consent for all handling or transfer of personal data. Therefore, consents are necessary before tissue, diagnosis or genealogical data is transferred to the NHGRC. The reason for this is that a transfer of information is a "handling" of information pursuant to the law on the protection of personal information. The requirement for consent can be waived in this instance, however, because such transfer is authorized pursuant to this Act. Pursuant to § 7, paragraph 1, it is possible to transfer diagnosis and genealogical data registries to the NHGRC without individual consent. An additional exemption to the requirement for consent is the transfer within the NHGRC itself. Information may not, however, be used for any research without individual personal consent.

Section 7, paragraph 1 is a continuation of the stipulation of the right of the NHGRC to offer the information it manages to others. What is specifically stipulated is that the information shall be evaluated as to its relevance and importance for genetics research. It should be noted that this provision does not address the information to which the Responsible Clinician, pursuant to paragraph 4, has access in order to determine if the diagnoses are correct. The NHGRC may only compile and store tissue samples, WHO classification codes of diagnoses and genealogical data.

To paragraph 3
No comments.

To paragraph 4
As circumstances are today, vast amounts of health-related data resides within the national hospital system, specialist physicians, the municipal physicians and the national pharmacy. It must be possible for the Responsible Clinician to gain access to this information subsequent to the approval of a research project by the Faroese Scientific Ethics Committee and the NHGRC. This access is necessary in order to ensure, as much as possible, the accuracy of the diagnostic information available from the national health care system. It should be noted that the Health Information, which is defined in § 2, is not anonymized at this stage. Therefore, it is important to note that the NHGRC, pursuant to this Act, does not handle Health Information per se, but only the anonymized diagnostic classification codes, which have been reviewed.

To paragraph 5
A prerequisite for genetics research is that relevant genealogical information be as complete as possible. As mentioned under the general comments above, the Faroe Islands is well positioned in

this regard, both because the Faroe Islands has been isolated during the centuries, and because relatively complete genealogical information is available.

In order to compile a Genealogy Registry, the NHGRC is authorized to gain access to the information available in the National Registry of Persons and the National Archives. Exactly how the Genealogy Registry shall be compiled and by whom is not decided, but the National Archives has demonstrated an interest to take on the necessary research work and compile a Genealogy Registry, pursuant to a negotiated agreement and appropriate remuneration. Once the Genealogy Registry is anonymized it shall be turned over to the NHGRC.

According to the legislative history related to the act on the protection of personal data, it is necessary to obtain permission to compile the Genealogy Registry from the Faroese Data Protection Board.

To § 8
Today, the health information, which the national hospital system has under its control, is consistent with the internationally recognized diagnostic classification codes. This means that the information that is submitted to the Diagnosis Registry is only neutral numerical data that stands for a classification of a specific disease or a specific health-related condition. Municipal physicians normally do not use this type of diagnostic coding. Thus, it will be necessary for the Responsible Clinician to transpose the patient data to the respective diagnostic codes.

Researchers that have been provided a DNA sample shall return the sample once the project is concluded.

To § 9
To paragraph 1
One issue is the administration by the NHGRC of the various registries, another is access to those registries. Pursuant to § 9, the NHGRC under no circumstances can allow access to the information contained in the registries without the Faroese Scientific Ethics Committee first approving a research project and the relevant requirements stipulated by the Faroese Data Protection Board, pursuant to the law on the protection of personal information, are fully observed. In both instances, requirements for informed consent are implicit. The regulations governing informed consent are based on the understanding that everyone has a unique, personal identity that shall be valued and respected.

As stated before, an approved contract or agreement is required before access to or use of the registries is permitted.

Here it should be noted that the NHGRC in each individual case may determine what specific conditions shall be stipulated in each agreement. If, for example, a research project does not anticipate any financial outcome from the research, the NHGRC may only require that the related expenses of the NHGRC be paid. On the other hand, if a research project does anticipate potential financial gain, then the agreement that the NHGRC negotiates may very well stipulate substantial advance payment or a percentage of the possible financial result.

To paragraph 2
Paragraph 2 is an exception to the principle rule stipulated in paragraph 1 above namely that access to the registries is permissible only upon the approval of a research agreement. It must noted that access to the registries maintained by the NHGRC granted in paragraph 2 only relates to the Diagnosis Registry and to the Genealogy Registry and **not to the Tissue Registry**.

The access that is granted here without an approved research agreement is for statistical purposes (registry research) and for preliminary research.

In both cases, the access involves statistical data and this authorization thus has nothing to do with pure genetics research. Pursuant to § 9, paragraph 2, no tissue samples may be used for preliminary research or for health-related research.

In paragraph 2, the NHGRC is granted the authority to conduct preliminary research on specific diseases to discover possible significant linkages between the Genealogy Registry and the Diagnosis Registry. These investigations could enhance the negotiating position of the NHGRC and increase the potential to craft a more positive research contract. The access granted under paragraph 2 requires, however, permission from the Faroese Scientific Ethics Committee and the Faroese Data Protection Board.

To § 10
The purpose of this provision is to set a limit on the use of testing that could indicate the presence of an hereditary disease by limiting the use of such research / tests to only those instances wherein the knowledge would assist in the treatment of an individual or in connection with health-related research, conditioned on the provision of relevant and appropriate genetic counseling for those concerned. Health-related research is included in the phrase "health-related purposes" found in § 10, paragraph 1. Thus, there is nothing that precludes research that seeks ultimately a financial gain, if the research also has a health-related purpose. In the Danish comments to the Convention, health-related purposes was phrased so that the content would be about "sundhedsrelaterede formal" [health-related purposes]. Research can thus be promoted as long as the research is also linked to health-related purposes, such as discovering disease-bearing genes in order to enhance treatment and thereby improve the health of people as a whole.

The rapid developments within hereditary research that has occurred over the last ten years have made it possible with much greater accuracy than before to identify people that are the carriers of a specific gene that is linked to major disease processes.

Based on the special problems that arise stemming from tests that could identify the possibility of the existence of an hereditary disease, it is deemed necessary to limit the use of such research / tests to health-related purposes.

The provision does not restrict access to fetal testing [such as amniocentesis] as long as the test has a health-related purpose or is linked to hereditary testing, for example, in connection with the employment of individuals, conditioned on that these tests have a health-related purpose that is related to the position itself or to other employees.

To paragraph 2
The purpose of this provision is to restrict the result of hereditary testing being used for baseless discrimination. The provisions sets forth a major principle that is based on the overarching principles of human rights conventions that prohibit discrimination because of gender, race, color, language, etc.

To § 11
Section 10 is designed to ensure that the information and samples in the registries administered by the NHGRC do not fall into the hands of unauthorized persons, but are rather fully under the control of the NHGRC. Therefore, unauthorized transfer is forbidden. Moreover, it is forbidden to lodge a complaint for attachment or seek a lien against the information or samples controlled by the NHGRC.

To § 12
To paragraph 1
This provision grants the authority to punish any violation of this special legislation. Furthermore, other relevant legislation is made enforceable in this matter. For example, violations of the requirement for transparency by the NHGRC and the national health care system are stipulated in the penal code, as well as, for example, computer break-ins, which are also regulated by the penal code.

These general provisions notwithstanding, it was deemed necessary to have very specific and strict provisions regarding the violation of this Act, violations that could well impair the security of the NHGRC and its activities.

To paragraph 2
This provision grants the authority to punish juridical persons (companies, etc.).

To paragraph 3
In order to secure the exclusive right and integrity of the NHGRC, it was deemed necessary to grant authority to the NHGRC to legally seize the tissue samples and the diagnosis data provided, stored, or otherwise handled in connection with a genetics research project, even though a research contract with the NHGRC may be in effect.

To § 13
This provision stipulates when the Act shall enter into force.

The following documents are available (in Faroese):

Document 1: Compilation of responses presented during hearings.
Document 2: Response from the Faroese Lutheran Diocese
Document 3: Response from the Faroese National Archives
Document 4: Response from the Ministry of Finance
Document 5: Response from the University of the Faroe Islands
Document 6: Response from the Ministry of the Interior
Document 7: Response from the Faroese Scientific Ethics Committee
Document 8: Response from the Ministry of Culture
Document 9: Response from the Jens Wang and Hannes Gislason
Document 10: Response from the Faroese Research Council
Document 11: Response from the Office of the Prime Minister
Document 12: Response from the Javni (Association for the Developmentally Disabled)
Document 13: Response from the MBF (Association for the Disabled)
Document 14: Response from the Ministry of Fisheries and Maritime Affairs
Document 15: Response from the Faroese Employers Association (House of Industry)
Document 16: Response from the Faroese Nurses Association
Document 17: Response from the Faroese Medical Association
Document 18: Response from the Faroese Data Protection Board
Document 19: Response from the National Hospital in Tórshavn
Document 20: Response from the Office of the Danish Representative to the Faroe Islands

First Reading of the bill occurred on 29 March 2005. The issue was referred immediately to the Social Welfare Committee of the Parliament, which reported as follows on 27 April 2005.

Committee Report

The Government submitted the bill on 4 March 2005 and subsequent to the first reading on 29 March 2005 the bill was referred to the Social Welfare Committee.

The Committee reviewed the bill at meetings held on 8, 13, 15, 20, 27 April 2005.

During its review, the Committee met with the Minister of Health and Social Services, Hans Pauli Strøm, representatives from Bitland, representatives from the Faroese Scientific Ethics Committee, representatives from MBF [Association for the Disabled] and Jens Waag and Hannes Gislason.

The Minister of Health and Social Services reported to the Committee that the bill now affords an individual the level of security that the members of Parliament had desired.

The Committee believes that it is necessary to ensure the development of a research environment in the Faroe Islands. The Committee feels that this development will generate a foundation for extended development with the area of genetics research and other biotechnology research, e.g. in aquaculture.

The Committee moreover believes that it is necessary to ensure a foundation for the development of Faroese business and industry.

With these stipulations, a unanimous Committee declares the following:

Proposed Amendments

1. In § 1, after the phrase " advance competencies within the Faroese National Health Care System", insert the phrase " establish a consummate research environment in the Faroe Islands".

2. In § 3, paragraph 2, the paragraph shall read as follows: "The National Human Genetics Resource Centre (NHGRC) has authority to enter into agreements regarding the study of information contained in said registries."

3. In § 3, after paragraph 2, the following paragraph 3 shall be inserted: "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."

   Paragraph 3 and 4 shall subsequently be referenced as paragraph 4 and 5.

4. In § 4, paragraph 4, the phrase "all cases" shall be amended to "each instance".

5. In § 4, paragraph 7, the phrase "as so" shall be stricken.

Comments to individual amendments:

1. Reference 1: it is intended that the purpose of the Act shall also be to encourage the advancement of a research environment as a whole in the Faroe Islands.

2. Reference 2: current paragraph shall be divided up into two sections and phrased in a more detailed fashion.

3. Reference 3: confer Reference 2

4. Reference 4: syntax correction

5. Reference 5: syntax correction

A unanimous Committee approves of the bill and recommends that the Parliament ratify the bill with the above-named amendments.

At a session of Parliament held on 6 May 2005, the following members of Parliament – Jørgen Niclasen, Andrias Petersen, Finnur Helmsdal, Lisbeth L. Petersen, Johan Dahl, Annita á Fríðriksmørk and Bill Justinussen – offered the following amendments:

Proposed Amendment at the Second Reading

In § 2, the phrase, "National Hospital" shall be amended to read "National Hospital System".

Comments:
The amendment is necessitated in order to ensure consistency in the wording in this Act with the phrasing in the law on the national hospital system.

Second Reading on 6 May 2005. The amendment proposed by Jørgen Niclasen, Andrias Petersen, Finnur Helmsdal, Lisbeth L. Petersen, Johan Dahl, Annita á Fríðriksmørk and Bill Justinussen to § 2 was approved 24-0-0. The proposed amendments from a unanimous Social Welfare Committee to §§ 1, 3, and 4 were approved 24-0-0. The bill as amended was approved 24-0-0. The bill was approved for submission to a Third Reading.

Third Reading on 10 May 2005. The bill, which was approved on its Second Reading, was finally approved 31-0-0. The bill is ratified into law.

Parliamentary Act No. 62, dated 17 May 2005.