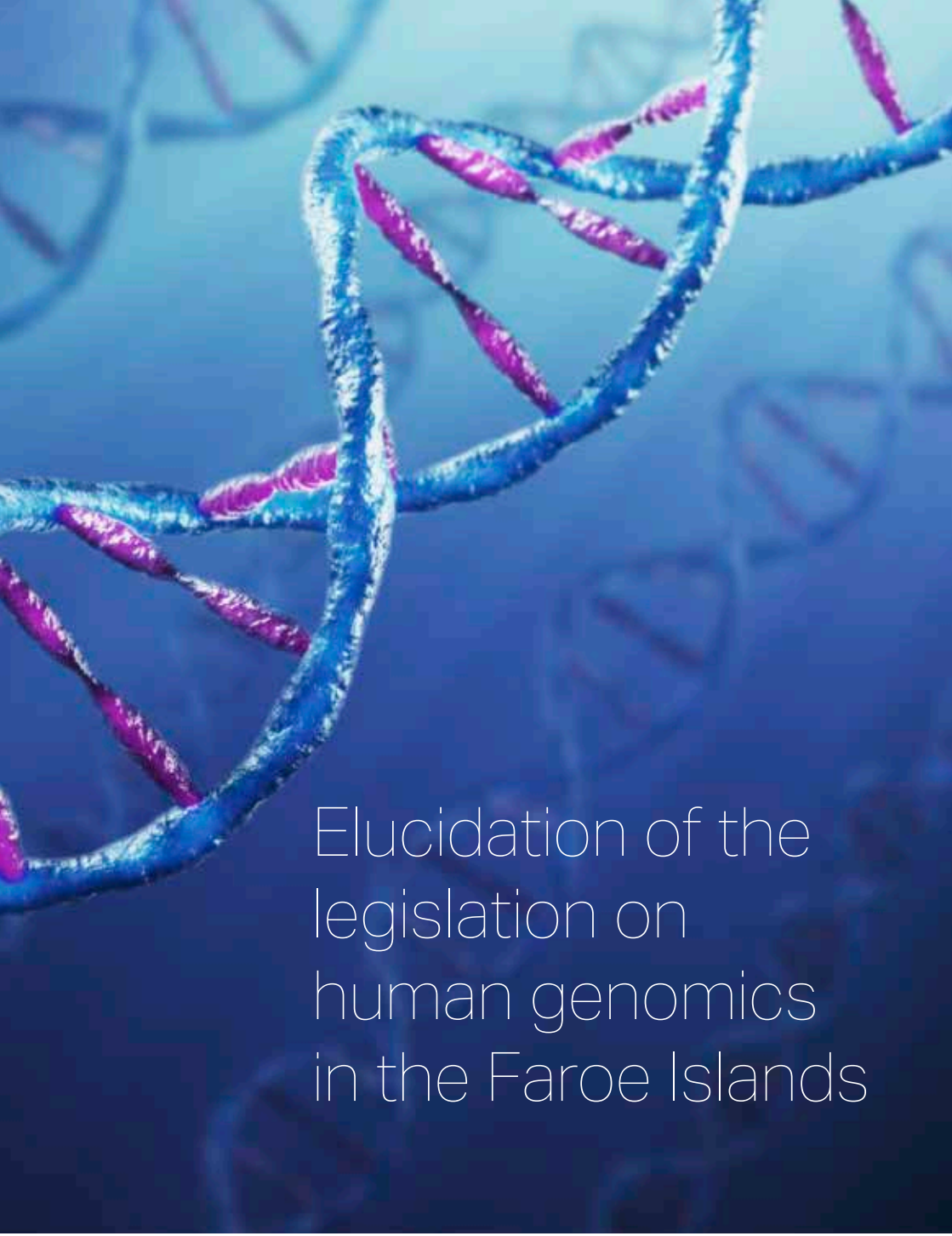

Elucidation of the legislation on human genomics in the Faroe Islands

HEILSUMÁLARÁÐIÐ
august 2015

Elucidation of the legislation on human genomics in the Faroe Islands

Heilsumálaráðið august 2015

Elucidation of the legislation on human genomics in the Faroe Islands

Umbrotið, prentað og heft: Føroyaprent
Útgevari: Heilsumálaráðið 2015

ISBN 978-99918-970-6-6

NORÐURLENDSKT UMHVØRVISMERKI
Svanamerktur prentlutur 541 705

2. Summary

2.1 Introduction

The mandate of the working group was to describe the current laws and legislation that protect the citizen in the context of genomic studies, and assess the possibilities and hindrances in the present laws to apply genomics in diagnostics, treatment and research.

Additionally, the group was given the assignment to analyse and assess whether the provisions of the current legislation are sufficient regarding the rights of autonomy of the persons who undergo such studies and the corresponding duties for health care workers to inform about incidental findings.

Last, but not least, the working group was asked to assess and to provide suggestions to revisions and changes of the current laws if needed to safeguard the citizen in relation to genomic studies and research.

2.2 On gene and genome

We inherit our genetic properties from our parents. The inheritance is based in our genetic material, the human genome.

The genetic material is often called DNA, an abbreviation for deoxyribonucleic acid, which constitute the building blocks of the DNA. All organisms, with exception of some viruses, have DNA as their genetic material.

The human genome tells us much about our health, our personal characteristics, both the good ones and the less good ones, and can be used for personal identification. Even anonymous genome sequences can identify persons down to name and address. It cannot be guaranteed that a genome sequence stays anonymous, in the sense that the sequence never could lead back to the donor.

It is a long way from genome sequencing to a complete genetic analysis that can tell us everything about our (potential) genetic diseases and other genetic characteristics. The genome sequencing in itself only gives an enormous amount of short sequences (in the area of one billion separate sequences), approximately like the single pieces in a big puzzle. It is at this step that the data in the FarGen project are to be stored.

Physicians and the health system are not at this point able to use the data in any meaningful way. The data must first be assembled into a complete genome. This is then compared with a reference genome, and all sequence variations are compared with the spectrum of known variations. Previously unknown variations must be analysed and interpreted, which might be a difficult task[1]. Only when the specialists have worked through all these steps and put their findings into an understandable text, can the genome sequences and the conclusions be used by the GP and the health system.

If genome sequencing is to be a future part of the health system and the patient's medical health record, it will be a strong incentive to develop user-friendly software tools that rapidly

can search through the sequences and find variations that are linked to diseases – first for common and monogenetic diseases, later for diseases of more complex genetic etiology.

2.3 Faroese health-related legislation

Most of the Faroese laws and regulations that protect the citizen in the context of genetic and genomic investigations are within the health area. In particular, the Parliamentary Act on Human Genetic Research ("Ílegulógin"), the Parliamentary Act on a Regional Committee on Health Research Ethics ("Lóg um Vísindasiðseminevnd") and Parliamentary Act on Patients' Rights ("Lóg um sjúklingarættindi") are important in these contexts. The conclusions of the working group regarding Faroese legislation within these areas are described below.

2.3.1 Laws on clinical biobanks

A biobank collects biological samples, like blood and tissue samples. The purposes could be storage, future use in clinics, research and other investigations. Often one distinguishes between clinical biobanks and research biobanks.

In the Faroe Islands, the Faroese Genetic Biobank ("Ílegusavnið") constitutes the research biobanks of human samples. The Genetic Biobank is a governmental institution located under the Ministry of Health. Its activities are determined and regulated by the Parliamentary Act No. 62 on Human Genetic Research from 17th May 2005.

The largest biobanks in the Faroe Islands are the clinical biobanks. These are the biobanks of the three Faroese hospitals. There are no Faroese Parliamentary Acts that regulate the activities of clinical biobanks.

In contrast to the other Nordic countries, there are no Faroese rules for allowances or license to make a clinical biobank. By license is understood that it requires authority approval to establish a clinical biobank. The authorities keep an overview of where the biobanks are located and what kind of samples are stored in the biobanks. Currently, there is no overview or registry of the clinical biobanks in the Faroe Islands.

The working group recommends that rules for clinical biobanks are to be made in the form of a Parliamentary Act, and this should include the approval of the biobanks. The Norwegian legislation in this area could give suggestions for such rules. The working group also recommends that a complete overview is to be made of the clinical biobanks that contain Faroese samples.

2.3.2 Parliamentary Act on Human Genetic Research ("Ílegulógin")

The working group has concluded that a number of changes will be needed in the Parliamentary Act on Human Genetic Research.

The law entered into force in 2005. The law has now been active for 10 years, and it is possible to evaluate whether revisions are required. In this report, the working group has discussed the law and suggests changes to the law.

The working group recommends revisions in the formulations used for the purpose of the law, in the frames of the law, and in the borders for the authorities and the tasks for the

Genetic Biobank relative to the Regional Committee on Health Research Ethics. The working group also recommends changes in the formulations of the exclusive rights of the Genetic Biobank and of the responsible clinician.

Furthermore, the organisation of the Genetic Biobank with a Tissue Registry, Diagnosis Registry and Genealogy Registry should be evaluated, especially having in mind the protection of the citizen. It should be decided whether the sequences and results from genome and microbiome investigations, should be taken care of in the Tissue Registry, or a novel registry should be established for these purposes.

Additionally, it should be considered to make rules for how complete genome information should be protected. In addition, it should be described in the Act that all genome sequences become a part of the Tissue Registry, in order to prevent that genomic investigations are used in registry-based research without permission of the Biomedical Research Ethics Committee. In this context, it should be considered whether the Tissue Registry should change name, so it better corresponds with the contents of the Registry.

2.3.3 Broad informed consent

In Sweden and Norway, it is stipulated in the law that the citizen has the opportunity to to provide a broad informed consent. Broad informed consent means that a citizen permits that his/her information (or genome sequence) can be used in various future research studies that are vaguely described. One example could be that the citizen permits researchers the grant to use the citizen's genome sequence in future cancer research. Included in the permit is also the possibility of the citizen to withdraw the permission. Broad informed consent is not mentioned in the Faroese legislation.

The problem with a broad informed consent is that the citizen with a single permission allows the use of his/her information or sample to be included in several research projects, without the specific knowledge of what the purposes of those projects are. Thus, the citizen might become participant in a research project that he/she for some reason would not like to support or be participating in.

Genome sequencing will additionally give enormous amounts of information about the participant, but also about the participants' family. Thus, an informed consent from one person in fact also affects other persons. The question is therefore if it should be possible for a person to give a detailed and informed consent for several future projects.

The working group recommends that the advantages and drawbacks with a broad informed consent are studied and discussed more before making a decision whether this should be a possibility on the Faroe Islands. The Swedish and Norwegian legislations could be a partial basis for such discussions. In this context should also be included the fact that the Faroese society may have particular challenges due to its small scale.

2.3.4 Information and genetic counselling for research participants

Presently, a participant in a research project that is using family relationship information has the right to genetic counselling according to § 10, para 1 in the Act of Human Genetic Research.

Genetic counselling emphasizes how the participant understands the situation, and how the participant adapts to and manages this situation. The National Society of Genetic Counsellors (NSGC) defines the term genetic counselling as "the process of helping people understand and adapt to the medical, psychological and relational implications of genetic contributions to disease."

The working group is of the opinion that the right to genetic counselling should be valid for both genetic diagnostics and research. It is important that a citizen, who is going to decide whether he/she should get information about his/her own genome or the genome of someone in his or her family, receives information from a genetic counsellor both before and after the study. In the view of the working group, the parents should be present during genetic counselling for children below 18 years of age.

It should also be considered how and who in the health care system should inform the family and relatives about a genetic disease. The information would be of particular importance if the disease could be prevented or treated with good results.

2.3.5 Feedback and the right to know or not to know

When a genome is sequenced and analysed, in principle there is information about all the genetic inheritance of the person, and thereby potentially information about disease predispositions that were not known beforehand. Thus, there are questions if the participant should have feedback about so-called incidental findings that could influence health, or whether the participant should have the right to stay uninformed.

The working group is of the opinion that the legislation in the Faroe Islands about the responsibilities of the health care system to inform about incidental findings is not satisfactory.

To take Norway as an example: In case of a serious genetic disease that can be treated, the responsible physician or health care worker should inform the person and the relatives that potentially could have the disease, even if the person did not want feedback.

If the disease is serious, but not treatable, the same requirement is not present. This is because such a feedback could affect the life quality of the person if they have the knowledge that a non-treatable disease affects them. If a treatment is discovered at a later point of time, the physician should inform the person and the relatives.

If the disease is not serious and there is only a small risk for the person to get the disease, the patient should not be informed, unless the patient wants feedback.

The working group recommends that the responsibilities of health care workers to inform about incidental findings should be further discussed, and it should be decided whether legislation similar to the one in Norway also should be made for the Faroe Islands. In this context, it should also be considered how this affects the process of informed consent and participation in a research project.

2.3.6 Protection of children and youth

Faroese legislation contains no provision with special regard to protecting children and adolescents when it comes to genetic examinations and genomic research. As genome

research has become more common in the countries around us, the Nordic countries are debating whether it should be possible to conduct genetic examinations on children.

The working group finds that children and adolescents are in a special position in terms of genetic research as they, when the genetic examination is being conducted, are not able to give unaided consent and are not able to understand, what this potential consent means. Genetic information can affect both the actual child and adolescent, but also several generations. It could therefore be considered that genetic examinations conducted on children will only be used for research when it is not possible to use genetic examinations conducted on adults, and when the research also is expected to provide concrete health advantages for the child in question.

However, the working group also is of the conviction that research in children's genomes in several cases can be important in terms of finding new information regarding genetic diseases in both children and adults. It is therefore difficult to give a clear recommendation regarding the protection of children.

New legislation in this field must take into account the rights of children to their genetic information but also the new information that results from research in children's genomes.

It is necessary to make a decision on whether there in the Faroe Islands should be legislation that protects the children, so that genetic research conducted on children will primarily only be used for genetic research, when the research is deemed to be of significance to the child itself, or if legislation regarding research in children's genomes should be the same as the provisions regarding adults.

2.3.7 Legislation regarding the Science Ethics Committee

The Parliamentary Act of Science Ethics guarantees that health research in the Faroe Islands is conducted in a safe and proper way. That the rights of the citizens of the Faroe Islands, and that the safety and well-being of the research participants, are guaranteed. At the same time, it also falls upon the Faroese Science Ethics Committee to ensure a solid foundation during the collection of new information in health research.

The law is established by a royal decree. If changes to the legislation regarding genetic examinations and research are required, the Danish authorities will have to take the initiative to change the legislation. The royal decree was updated in 2013 in order to be aligned with the current Danish legislation.

Several executive orders have been put into effect in accordance with Danish legislation. Of special importance to genetic research are the rules on information and consent given in the orders: "Bekendtgørelse om gebyr for videnskabsetisk behandling af sundhedsvidenskabelige forskningsprojekter" and "Bekendgørelse for Færøerne om information og samtykke til deltagelse i sundhedsvidenskabelige forskningsprojekter samt om anmeldelse af og tilsyn med til sundhedsvidenskabelige forskningsprojekter".

The working group recommends that these executive orders are put into effect in the Faroe Islands, and that the law of science ethics from now on is updated when the Danish equivalent law is updated.

2.3.8 Legislation regarding the rights of patients

In the Parliamentary Act on Patients' Rights: "Anordning om ikrafttræden for Færøerne af lov om patienters retsstilling" there are provisions on patients self-determination rights in connection with treatment in the health care system and elsewhere. The law is also valid for participants in research projects in the area of genetics. It is stated in the law, § 4, para 3, that a person who hands over tissue to the Genetic Biobank is to be seen as a patient in health treatment under the Parliamentary Act of Patients' Rights.

The provisions in the law on informed consent are of special importance. According to these provisions, a patient has the right to informed consent prior to the treatment. The patient may withdraw this consent at any time. The law is of importance in protecting the individual patient and for the individual person's right to self-determination concerning genetic research and treatment.

Since the law was enforced in the Faroe Islands, the Danish law has been changed. There are e.g. provisions on a Register for the use of tissue. In this registry, a patient may register a decision that says that biological material, which the patient has handed over in connection with a specific treatment, can only be used for treatment of this person and for purposes connected to this treatment.

In addition to this, a number of executive orders have been enforced under the provision of the Danish law. It is of importance to the defence of patient's right to self-determination to adopt the order on the subject: "bekendtgørelse om information og samtykke og videregivelse af helbredsoplysninger".

It is not possible to make changes in the royal decree on patient's rights, because the law has been nulled in Denmark. Provisions on patients' rights are now to be found in the "Health Act". It is possible though to introduce a law to the Faroese Parliament on patient's rights and make the necessary adjustments and changes in this proposed law.

The working group suggests that a law proposal on the patients' rights is set forth and enforced based on the present royal decree on Patients' Rights. Furthermore, the working group suggests that similar provisions on a Registry on the use of tissue and the provisions in the before mentioned executive order be enforced in the Faroe Islands.

2.3.9 Legislation on the Council of Ethics

There is no Council of Ethics in the Faroe Islands, which can create public debate and inform the public on ethical issues e.g. in connection with genetic research or which can advise in ethical questions on genetic research and genetic analysis. France was the first country to establish a Council of Ethics, this happened in 1983, followed by Sweden, Denmark and other countries. Today, most countries in Northern Europe have established a Council of Ethics.

The recent debate on genetic research in the Faroe Islands and on the idea of mapping the genome of all Faroese citizens has raised the question whether a Council of Ethics should be established in the Faroe Islands. It was in this context that the Welfare Committee of the Faroese Parliament in spring 2013 recommended the Minister of Health to start the preparations for a Council of Ethics in the Faroe Islands. A Parliamentary Act was drafted and proposed to the Faroese Parliament in March 2014. The proposal was withdrawn prior to the discussion due to limited political backup.

The working group recommends the establishment of a Faroese Council of Ethics based on the legislation on Councils of Ethics in our neighboring countries. The tasks of the Council of Ethics must be to create and strengthen debate and knowledge on ethical questions, especially in the areas of genetic research and genetic analysis.

2.3.10 Legislation on medical equipment

There are provisions on medicine in "Parliamentary Act No 104 of 5 September on Pharmacy Service and Medicine" with later changes. There are no provisions on medical equipment in the Faroe Islands. In Denmark, there is an "Act on Medical Equipment"[ii] with executive orders attached. In the legislation, there are provisions on the professional standards of medical equipment and how equipment is approved. In addition there are regulations stating that some specific medical equipment may only be delivered through pharmacies and in specific cases only by instructions from medical doctors or dentists.

The working group thus recommends that a law proposal on medical equipment is set forth and enforced, so there will be professional standards set to medical equipment in the Faroe Islands. Another possibility is to include instructions on medical equipment in the Parliamentary Act on Pharmacy Service and Medicine.

2.4 Church Affairs, Archival Affairs and Archeological Affairs

Amongst the areas that the Ministry of Culture administers and which in some way are relevant to genetic research are research, church affairs, archival affairs and archeological affairs. In the area of church affairs there are the church registries which hold the basic personal registrations many hundred years back. This information is of vital importance to genetic research as an element in the genetic research is to connect information on our genetic heritage to information on family relations.

The National Archives administer all archival matters. The National Archives decide on the basis on the legislation on the National Archives, who may access the preserved documents of the Archives. These documents include church registries, patient records, midwife journals and other records, which public authorities produce during their administration and decision-making. In the area of archeology, a question has been raised on how archeological genetic research is to be seen in the light of the Parliamentary Act on Human Genetic Research.

2.4.1 Church Affairs

The Faroe Islands have kept church records for several hundred years. The oldest Faroese provisions stating that priests must keep ministerial records are to be found in the so-called Norwegian Act, initiated by King Christian the fifth in 1687. The national church jurisdiction was transferred from the Danish State authorities to the Faroese Home Rule authorities valid from 29 July 2007. The regulations on church records and access to these records are to be found in "Circular letter on the National Church's and the Approved Religious Communities' records" (Circular letter No 123 of 14 August 1987).

The authorization for the circular letter to keep church records, including the access rights, is to be found in legal customs, prior to the Danish Constitution from 1849. The same circular letter with small changes is still valid in Denmark, but in reality, it has no function in regulating the access, because all the church records are transferred to the Danish National

Archives. All access to church records in Denmark is regulated according to the Archival legislation.

We therefore are in a position where the citizens' rights are limited based on a Danish circular letter which has no practical importance in Denmark. According to the Act on the National Archives personal information is accessible after 80 years. As long as the registries are kept by the Church, the legal position is different, here personal information are only accessible after 110 years.

The working group recommends that it is decided and clearly stated in legislation, when personal information, including personal information kept in Church records, are to be accessible.

The legislation on birth and death is old and the working group is of the opinion that the legislation needs to be improved. The working group recommends that new legislation is drafted and enforced in this area. In this connection, it would be wise to consider the future role of the National Church in the birth and death notification and registration

2.4.2 Archival affairs

Archival affairs are regulated in the Act on the National Archives with executive orders attached Even though the legislation covers the basic need, improvements and updates are required. The working group finds that it would be timely to draft a new act on archives, replacing the present act and executive orders, giving the National Archives wider authority to set rules for preservations. It is imperative that a new law on national archival affairs and the law on personal information are coordinated, so they are not contradicting each other.

The working group believes that the question of access for genetic research purposes ought to be discussed, in order to ensure safer and easier access to selected groups of sensitive personal information. It should e.g. be looked into advantages and disadvantages in regulating by law or by special arrangement:

- concerning the Faroese sources (church records, national registers, medical journals, midwife protocols), according to the law on genetic research or other legislation,
- concerning the Danish sources (e.g.censuses), according to specific agreement with the National Archives or other relevant authority.

The restrictions on access must be unambiguous in order to assure that this general permission to access is not abused.

The working group finds that the issue of access to and usage of the available material in the Family Registry and possible other basic registries kept by the National Archives must be examined, especially to give the opportunity to use the information for other purposes than genetic research, e.g. based on the stipulation in the law on archival matters.

2.4.3 Archaeological affairs

Concerning archaeological matters, the working group recommends that the relevant Ministries and institutions look at whether cases of archaeological human relics older than e.g. 100 years, should be covered by the legislation on human genetic research or by the

archaeological legislation. The discussion must take into consideration the relevant ICOM guidelines.

The Parliamentary Act on Human Genetic Research dates from 2005, when the church records still were under Danish authority. Since 2007 the church records have been under Faroese authority. The working group therefore recommends that provisions are included in § 7, para 1 on access to information from the national records.

2.5 Business legislation in the genome field

The immaterial legislation contains regulations regarding patent of the human body and states that it is not possible to patent the human body, including a gene or sequence of a gene. On the other hand, the patent law and the law of utility models state that if an inventor, who e.g. has identified a DNA-sequence and explained the function of the sequence, the industrial production and use can be patented. The immaterial legislation was updated in 2015 and is pertinent to the question of patenting the human body in accordance to what is in force in our neighbouring countries.

One question regularly discussed in regards to genetic examinations is whether insurance companies can demand insight into this information about our family characteristics when taking out insurance. Based on the current legislation, the Ministry of Trade and Industry has analysed this question.

When a policy holder asks for endowment insurance, share insurance or annuity insurance, the insurance companies need and have the right to receive medical information regarding the policy holder. The conclusion is, after a precise exposition of the jurisdiction and the legislation covered by the Ministry of Trade and Industry and its institutions, that the Ministry of Trade and Industry in the legislation has no provisions that allow genome examinations or research, as part of genome examinations.

In Denmark it is the Insurance Agreement Law (Forsikringsaftaleloven) that stipulates which health information insurance companies and pension funds can use when judging the third-party risk of the person in question. It is especially the provision in § 3a that is different in the Faroese insurance agreement law compared to the Danish equivalent.

The insurance company and the pension fund may collect, receive and use information regarding present and past illnesses, the communication with doctors and other caseworkers. The company may also collect, receive and use information regarding present illness or illness found in others, e.g. information regarding so-called family anamneses of relatives.

On the other hand, legislation clearly states that insurance companies and pension funds cannot collect, receive and use information that examines the genomes of a person and the risk of developing an illness in the future, according to § 3a in the Danish insurance agreement law.

This provision is not in the Faroese version of the insurance agreement law. There are no limits in the Faroese insurance agreement law regarding the possibilities for insurance companies and pension funds to use health information neither when an insurance agreement or a pension agreement is established nor regarding the possible termination of the agreement or change of the terms of an insurance or a pension.

The Working Group therefore advises that § 3a in the Danish insurance agreement law shall be enforced in the Faroe Islands.

2.6 Personal information

The Act on Personal Information is under the authority of the Prime Minister's Office. The purpose of the law is to guarantee the protection of individuals when processing personal information. Thus personal information is to be processed in respect of individual freedom and home privacy, based on high quality personal information. The core in the protection of the individuals is the right to self-determination. This means that a person as a leading principle has the right to decide which personal information other people should be able to access.

Part of the task of the working group was to estimate whether it is necessary to enforce new legislation and/or to insert special provisions in the Act on Personal Information in the area of genetic analysis. The working group was inspired by the debate in Norway on this issue. The Norwegian Act on Personal Information is quite similar to the Faroese Act. The Norwegian Data Protection Agency classifies genetic information as "especially sensitive information". This is due to the fact that genetic information provides a tremendous amount of new knowledge on biological material in each individual.

Furthermore, it not clear what information will be possible to retrieve from the genome in the future with new tools, working methods and knowledge. The Norwegian Data Protection Agency believes that special protection on the individual's right to self-determination on his/her own biological material ought to be included in the Act on Personal Information.

The working group agrees that due to the limited size of the Faroese society and that most Faroese citizens somehow are blood related, genetic information in the Faroe Islands must be regarded as especially sensitive information. The Faroese Act on Personal Information should have provisions concerning especially sensitive information.

As to the question of informed consent, the working group believes that there are special challenges in the area of genetic analysis, because it may be difficult for the registered individual to be able to fully understand the scope and consequences of informed consent in this connection. The obligation to inform must therefore be examined closer, and special provisions on consent ought to be enforced in this area. It is also necessary to consider and decide how relatives of the registered person should be handled, because a genomic analysis provides a huge amount of information on the registered person, but also indirectly on the relatives.

The working group recommends that provisions are included in the Act on personal information on especially sensitive information. It should be enforced by law that citizens must give a direct and informed consent when his/her genomic information is given to registries, e.g. biobanks, and that the citizen must have the right to refuse the registration of his/her information. It is also necessary to closely examine the duty to disclose information in connection with genomic analysis and that specific provisions on consent are enforced in this area. Furthermore, it must be decided whether specific consent must be given in order to give information to research projects etc. or the consent to give genomic information to registries also includes research projects.

2.7 Conclusion

In the Faroe Islands, there is a legislation that protects the citizens in the area of genetic research and genetic analysis. This includes especially the Parliamentary Act on a Regional Committee on Health Research Ethics, the Act on Human Genetic Research, the Act on Patients' Rights and the Act on Personal Information.

In this report, the working group has found it necessary to recommend a number of changes in the before mentioned legislation in addition to enforce new legislation in the area. This is believed necessary in order to strengthen the protection of citizens in the area of genetic research and genetic analysis.

The working group believes that the legislative changes recommended in this report may be done at the same time as a number of running genetic research projects are continuing.

[i] Dewey, F.E., et al., Clinical interpretation and implications of whole-genome sequencing. JAMA, 2014. 311(10): p. 1035-45.
[ii] LOV nr 1046 af 17/12/2002 om medicinsk udstyr