Information for participants about FarGen

Introduction
Thank you for registering to participate in the FarGen project. We would hereby like to invite you to take part in this project, which is managed by the Genetic Biobank of the Faroe Islands. In this document you will find information about the FarGen project and the potential benefits and risks of taking part. Please read this briefing carefully, so that you have a basis for deciding whether to consent to take part. All participation is voluntary and you can withdraw your consent at any given time.

Project
FarGen is a project managed by the Genetic Biobank, which is a body under the Ministry of Health. The Genetic Biobank is responsible for the FarGen project.

The FarGen project has two main components:

1. FarGen: A project managed by the Genetic Biobank that aims to sequence the genome of all the Faroese people who would like to take part.
2. Reference genome: A project managed by the Genetic Biobank for the purpose of generating a Faroese reference genome.

Purpose
The aim of the FarGen project is to sequence the DNA strands (genome) of any Faroese people who would like to take part. The purpose is to develop a platform that will generate opportunities for research using Faroese genes. Coupled with knowledge from the public health services and the Registry of Genealogy mapping Faroese genes will foster opportunities to improve prevention and treatment of medical conditions in the Faroese public health services. Given that this is the first study of this kind in the Faroes, the goal is also partly to develop local capacity to prepare DNA for genome sequencing, as well as to securely handle and store digital data from sequencing.

In the first phase the genomes of 1,500 Faroese people will be sequenced and the digital data obtained will be registered in the Genetic Biobank’s database. The data will be used to generate a Faroese reference genome. There will be no examination of what the results might say about any medical conditions or inherited traits you may have.

At a later stage you may be offered to take part in one or several concrete research projects, but on every occasion it will be up to you to decide whether or not you would like to participate in each separate project.

Genetic research
Some hereditary conditions are more common in the Faroe Islands than in the rest of Europe. This is due to the country’s remote location and the fact that most Faroese people descend from relatively few settlers. Genetic studies of the Faroese have confirmed that the Faroese population can be considered a
genetically isolation population, which means that it is uniquely suited to genetic research.

Great technological advances have been made in genetics in recent years. It is now possible to sequence both quickly and relatively cheaply an entire genome in one go. This means that all known genes can be studied at the same time. Such studies have provided insight into both ordinary and rare DNA mutations and increased our knowledge about medical conditions. Genome testing can therefore benefit both prevention and treatment offered by public health services.

Benefits of FarGen
The purpose of the FarGen project is to generate a database containing digital data on the genome of the Faroese population. The aim is also to develop the Genetic Biobank’s research infrastructure.

This database will establish the preconditions for and foster research in Faroese genes, so that such research can contribute to develop the Faroese research environment and the capacity to prevent and treat medical conditions.

One concrete outcome of the FarGen project will be the production of a reference genome. This is an important tool in genetic research. A Faroese reference genome can be used as a reference or basis for comparison for future genetic testing of individuals or patient groups. In addition, it can also provide an indication of which hereditary mutations are most common in the Faroes.

Potential risks for participants
The risks that may arise from taking part in the project are mainly:

- that breaches of confidentiality and data security can occur
- that hackers and thieves might access the data
- that although this project does not examine any individual for concrete medical conditions or specific genes, genes that could cause serious illness may be detected by chance. If it is possible to prevent or treat a genetic condition identified by chance, the clinician responsible has a duty to inform you and to offer you expert counselling.

Data security
The FarGen project complies with the customary standards of confidentiality and data security when gathering samples for the Genetic Biobank’s Registry of Tissue. The activities of the Genetic Biobank are mandated by Parliamentary Act 62, dated May 17, 2005, on Human Genetics Research.

Information about your genes is considered particularly sensitive personal data, and FarGen handles data in accordance with the Personal Data Protection Act. All sensitive personal data will be encrypted or protected by other means, e.g. anonymisation.
A clinician responsible for FarGen will administrate the records detailing who participates in the study and what data belongs to each participants, but otherwise you are protected by anonymisation.

If a research project is launched that needs your data in the FarGen database (held by the Genetic Biobank), your consent will be required in order for that project to access your data. You are always entitled to clear information about the purpose of the research project. Such a research project must always be authorised by the Genetic Biobank, Research Ethics Council and Data Protection Agency before it can start, and access will only be granted to anonymised data.

Your participation will be kept strictly confidential in all publications from each study and no personal data will be published. Anonymity can, however, be breached under circumstances of varying probability, for example if someone violates the code of confidentiality or hackers and thieves breach the anonymity.

Feedback
In this project your genome will be sequenced and digitalised and possibly used to generate a Faroese reference genome. There will be no study of what the data say about each individual’s potential medical conditions or traits. Furthermore, the data will only processed globally and nothing can therefore be reported back about your concrete hereditary characteristics. You will therefore not receive any feedback about your participation in this project; this means that you will not be notified of any results after your genome is sequenced.

It is, however, possible that genes that can cause illness are identified by chance. If there is certainty that such an illness can be prevented or treated, the clinician responsible has a duty to notify you about this and ensure that you receive a detailed explanation and genetic counselling. If you cannot accept these conditions, then you should not take part in this project.

Any such notification will be made based on a thorough medical assessment carried out in consultation between the doctor, who is the clinician responsible for the project, and at least one independent expert in genetic diseases.

Ethical conditions for this study
The Faroese Research Ethics Council authorised this project on August 1, 2016. The conditions for authorisation laid down by the Council include a requirement that all participation in this study must be based on written and oral information about the study, as well as the potential risks and benefits. In addition, the Council requires the study to comply with the ethical guidelines for studies that are covered by the concept “extensive mapping of the individual’s genome”.

Procedure
If you agree to take part in the project a bioanalyst will come to your town or village to draw a sample of your blood (20 ml). The only risk of having your blood drawn is tenderness of the area where the syringe is inserted. Your DNA will be extracted from the sample of blood and then read using a sequencing machine. The result of this reading is millions of fragments of your genome,
which are then put together into your concrete genome. The digitalisation of your genome will be carried out at the Genetic Biobank, and the anonymised data will be stored by the Genetic Biobank in compliance with the applicable legal framework. The blood sample will be stored in the Genetic Biobank's Registry of Tissue.

Your data may also be used to generate a Faroese reference genome. A reference genome is generated based on the genomes of several people and the Faroese reference genome will mainly be put together using data from so-called trios, namely mother, father and child. The purpose of generating a Faroese reference genome is to identify the average genetic composition of the Faroese population and with data from the before mentioned trio's we can also identify new Faroese variations. Data will only be processed globally and we can therefore not say anything about your concrete hereditary traits. You will therefore not receive any feedback about the genome analysis.

The first blood samples are scheduled for spring 2016 and we aim to sequence the genomes of the first 1,500 Faroese people by summer 2017.

Withdrawal
Participation in this project is voluntary. You can withdraw from the project at any time and request that your blood sample be disposed of. You will not be required to provide any explanation or reasons for your withdrawal. You may also request to have your blood sample returned to you, but a special reason would be required for this, such as other medical treatment or testing.

Please contact the Genetic Biobank if you wish to withdraw from the project. If you withdraw your consent to participation, this will in no way affect any future treatment you may receive in the public health service system. Data that has already been used for a project will be kept. Any unused data will be deleted.

Funding
No financial interests are linked to the project and there is no intention to use the data generated for any commercial purposes such as sale of the data.

The FarGen project is funded by the Danish Parliament, which has allocated DKK 10 million over a two-year period to sequence the genome of the 1,500 Faroese people.

The money needed to generate the Faroese reference genome has not yet been secured, but work is underway to seek funding.

Access to test results
You will not be given any access to test results in this project.

Clinician responsible
MD Bjarni á Steig, Consultant, is the clinician responsible for the project. This means that he is responsible for the clinical and genetic counselling of participants in the test, as well as for the collection of blood samples.
Participation
As a condition for participation, you will be required to submit a document known as an informed consent. By submitting this document you confirm that you consider yourself to have received adequate information about the project and about your participation in it. If you would like to participate you will be asked to sign and submit the annexed document “Declaration of consent” to us when the blood sample is drawn. You will also be asked to complete a questionnaire, which will contribute to strengthen the FarGen infrastructure of the Genetic Biobank.

If you have registered to participate in the project, but have changed your mind, you will be asked to notify the information coordinator:

Katrin D. Apol
Tel: +298 23 30 51
katrin@fargen.fo

Contact
If you need any further information about the project, please contact the FarGen project manager:

Noomi Oddmarsdóttir Gregersen, PhD in Molecular Biology
Tel: +298 23 30 50
noomi@fargen.fo

If you need clinical or genetic counselling or you have any questions about having your blood drawn, please contact the clinician responsible for the project:

MD Bjarni á Steig, Consultant
Tel: +298 23 45 25
lsbjast@ls.fo

Yours sincerely,

MD Bjarni á Steig, Clinician Responsible Noomi O. Gregersen, Project Manager
Consultant PhD in Molecular Biology

Guðrið Andorsdóttir
Director of the Genetic Biobank
DECLARATION OF CONSENT

to participate in the FarGen project:

PARTICIPANT DECLARATION:
- I have received written and oral information about the FarGen project
- I have had the opportunity to ask questions and have received satisfactory answers
- I know enough about the purpose, procedure, benefits and risks to confirm participation
- I have received information about the fact that participation is voluntary and that I can always, and without providing any explanations, withdraw from the study without this having any impact on my entitlement to use the public health services
- I have been offered genetic counselling from the clinician responsible
- I accept that if by chance genes that can cause a medical condition are detected, and provided that there is certainty that this condition can be treated or prevented, the clinician responsible has a duty to notify me of this and provide me with detailed information and counselling.

I hereby consent to take part in the FarGen project and to donate a sample of blood in order for my genome to be sequenced, and I consent to data from my blood sample being stored in the Genetic Biobank's Registry of Tissue and to it being used to generate a Faroese reference genome. My data may also be used in future research projects, provided that I consent to this in each individual case. I hereby also confirm that I have received a copy of the declaration of consent, as well as written information.

___________________________   ____________________________
Name (block letters)           P-tal
(Faroese personal identification number)

___________________________   ____________________________
Date                        Signature

DECLARATION BY THE CLINICIAN RESPONSIBLE
I hereby confirm that the participant has received oral and written information about the study. The participant has had the opportunity to put questions to me. I am persuaded that adequate information has been provided to enable a decision to take part in the project.

___________________________
Name (block letters)

___________________________   ____________________________
Date                        Signature