folkhälsan

PRIVACY POLICY/NOTICE
FOR SCIENTIFIC RESEARCH
EU General Data Protection Regulation
Art. 13 and 14

Information for Research Participants

You are taking part in a scientific study organized by the Samfundet Folkhälsan, Folkhälsan Research Center. This notice describes how your personal data will be processed in the study.

Participation in the study is voluntary. There will be no negative consequences for you if you choose not to participate in the study or if you withdraw from the study. However, if you withdraw from the study, data collected prior to your withdrawal may still be used in the study. For more information on your rights and how you can affect the processing of your personal data, please see section 17 of this notice.

1. Data Controller

Samfundet Folkhälsan i svenska Finland r.f. (”Folkhälsan”)
Address: PB 211 (Topeliuksenkatu 20), 00251 Helsinki

Contact person in matters concerning the project:
Name: Dr. Carina Wallgren-Pettersson
Address: The Folkhälsan Department of Medical Genetics, Topeliuksenkatu 20, 00250 Helsinki
Telephone: +358 44 788 6047
E-mail: carina.wallgren@helsinki.fi

2. Description of the study and the purposes of processing personal data

The purpose of the research to unravel the inherited (genetic) factors causing nemaline myopathy; novel genes, in which changes cause nemaline myopathy, and changes in the already known nemaline myopathy genes. In the centre of the research lies the nebulin gene, changes in which are the most common cause of nemaline myopathy. In this study, we use samples from the research participants and possibly from their close relatives. Sample types used are blood and DNA samples, muscle and skin biopsies, and other similar biological samples. The muscle biopsies have most often been taken in the context of the diagnostic process.

In addition, we collect information related to nemaline myopathy regarding the participants. Examples of such collected information is the degree of muscle weakness in different muscles, breathing, any joint contractures and what the muscle biopsy looks like (in case one has been performed). The information is collected using the participant’s information form, which the clinician caring for the patient completes on request by the research group. The aim of this form is to investigate the symptoms of nemaline myopathy and their relation to, for example, the genes and genetic changes that cause nemaline myopathy, in order to improve the

planning of the care of patients with nemaline myopathy and the development of genetic or other therapies.

The results gained through the research participants and their families and the information of the causative genetic variants are handled confidentially. When the sample and the preliminary information is received by the research group, each participant is assigned a research identification number. Names or other identifiable information is not used. The information is accessed and handled by the research group only using the research identification number, and only the principal investigator and the research assistant have the right to access and handle personal information when needed. Researchers are acting under professional secrecy.

If needed, consulting other parties in the interpretation of results may happen. In that case, all results are shared without personally identifiable information, so that the data cannot be linked to the original person. In these cases, only information necessary for the consultation are shared with persons outside the research group.

3. Parties and their responsibilities in research collaboration

None.

4. Principal investigator or research group

Name: Dr. Carina Wallgren-Pettersson
Address: The Folkhälsan Department of Medical Genetics, Topeliuksenkatu 20, 00250 Helsinki
Telephone: +358 44 788 6047
E-mail: carina.wallgren@helsinki.fi

5. Contact details of the Data Protection Officer

The Data Protection Officer of Folkhälsan is Johan Huldén. You can contact him by sending an e-mail to the address: dataskydd@folkhalsan.fi

6. Persons processing personal data in the study

The researchers and research assistants in the research group.

7. Name, nature and duration of the study

Name of the study: The Study on Nemaline Myopathy and Related Disorders

☒ One-time research ☐ Monitoring study/longitudinal study

Duration of the processing of personal data:

Personal data is processed until the research is finished (until the year 2050).

8. Lawful basis of processing

Personal data is processed on the following basis, which is based on Article 6(1) of the General Data Protection Regulation:

☒ **Participant's consent**
☐ compliance with a legal obligation to which the controller is subject
☐ performance of a task carried out in the public interest or in the exercise of official authority vested in the controller:
    ☐ scientific or historical research purposes or statistical purposes
    ☐ archiving of research materials or cultural heritage materials
☐ legitimate interests pursued by the controller or by a third party
    description of the legitimate interest:

9. Personal data included in the research materials

Data collected about the participant includes data on the possible genetic factors causing nemaline myopathy (or a similar muscle disorder) or affecting the patient's clinical picture. For the study, diagnostic findings based on the muscle biopsy and information about the participant's muscle symptoms and/or their progression, and information related to the heredity of the disease. In addition, the participant's name, reported gender and date of birth are registered.

10. Sensitive personal data

The following sensitive personal data will be processed in the study:

☒ Racial or ethnic origin
☐ Political opinions
☐ Religious or philosophical beliefs
☐ Trade union membership
☒ Genetic data
☐ Biometric data for the purpose of uniquely identifying a natural person
☒ Health
☐ A natural person's sex life or sexual orientation

Sensitive data is processed on the following basis, which is based on Article 9(2) of the General Data Protection Regulation:

☒ Consent of the participant
☐ Scientific or historical research purposes or statistical purposes
☐ The sensitive data has been made public by the participant
☐ Other:

☐ Personal data relating to criminal convictions and offences or related security measures will be processed in the study.

11. Sources of personal data

Information regarding the participant is collected using the research information form that is completed by the treating clinician.

Biological samples from the participant (see paragraph 2) are collected by the participant's healthcare system or its partners, according to instructions by the physician caring for the patient.

If previous biological samples have been taken from the participant or results from previous studies they have participated in exist, these results may be sent from the original party to the research group. This possibility is only used in terms of samples and results that are relevant for nemaline myopathy and related disorders and to nemaline myopathy research.

12. Transfer and disclosure of the personal data to third parties

The research group may send DNA samples to another laboratory for analysis in case the research center lacks access to the necessary methods. In such case, the samples are sent numbered without other identifiable data. If it is important for the research or for the participant to receive an outside expert's opinion, information is handled without personally identifiable information.

13. Transfer or disclosure of personal data to countries outside the EU/European Economic Area

If necessary, DNA samples may in some cases be sent to collaborators in e.g. Australia and/or the USA, if a method needed for taking the study forward is available in that country.

The cooperation contract with the service provider (collanborator) in question entails the EU Commission's standardized data protection rules in accordance with Article 46 (2), see https://ec.europa.eu/info/law/law-topic/data-protection/data-transfers-outside-eu/model-contracts-transfer-personal-data-third-countries_en

14. Automated decisions

No automated decisions are made.

15. Safeguards to protect the personal data

☒ The data is confidential.

Protection of manual material:

Information existing in print on paper is stored in a locked archival cabinet in a locked room.

Personal data processed in IT systems:
☒ username ☒ password ☒ logging ☒ access control
☒ other: When logging in to the IT-system the researcher receives a single-use code to their mobile phone. Without the single-use code, no access is granted to the system.

Processing of direct identifiers:
☒ Direct identifiers will be removed in the analysis phase
☐ The material to be analyzed includes direct identifiers. Reason: (reason for retention of direct identifiers

16. Processing of personal data after the completion of the study

☐ The research material will be deleted
☒ The research material will be archived:
☐ without identifiers ☒ with identifiers

Where will the material be archived and for how long:

The material is archived in a centralised database existing on a secure server until the study is finished, approximately in the year 2050.

17. Your rights as a data subject, and exceptions to these rights

The contact person in matters concerning the rights of the participant is the person mentioned in section 1 of this notice.

Withdrawing consent (GDPR Article 7)
You have the right to withdraw your consent, provided that the processing of the personal data is based on consent. The withdrawal of consent will not affect the lawfulness of processing based on consent before its withdrawal.

Right of access (GDPR Article 15)
You have the right to obtain information on whether or not personal data concerning you are being processed in the project, as well as the data being processed. You can also request a copy of the personal data undergoing processing.

Right to rectification (GDPR Article 16)
If there are inaccuracies or errors in your personal data undergoing processing, you have the right to request their rectification or supplementation.

Right to erasure (GDPR Article 17)
You have the right to request the erasure of your personal data on the following grounds:

a. The personal data are no longer necessary for the purposes for which they were collected or otherwise processed.

b. You withdraw the consent on which the processing was based, and there are no other legal grounds for the processing.

c. You object to the processing (the right to object is described below), and there are no justified grounds for the processing.

d. The personal data have been unlawfully processed, or

e. The personal data must be erased to comply with a legal obligation in Union or Member State law to which the controller is subject.

The right to erasure does not apply if the erasure of data renders impossible or seriously impairs the achievement of the objectives of the processing in scientific research.

Right to restriction of processing (GDPR Article 18)
You have the right to restrict the processing of your personal data on the following grounds:

a. You contest the accuracy of the personal data, whereupon the processing will be restricted for a period enabling the Data Controller to verify their accuracy.

b. The processing is unlawful and you oppose the erasure of the personal data, requesting the restriction of their use instead.

c. The Data Controller no longer needs the personal data for the purposes of the processing, but you need them for the establishment, exercise or defence of legal claims.

d. You have objected to processing (see details below) pending verification of whether the legitimate grounds of the controller override those of the data subject.

Right to data portability (GDPR Article 20)
You have the right to receive the personal data you have submitted to the Data Controller in a structured, commonly used and machine-readable format and have the right to transmit these data to another controller without hindrance from the Data Controller, provided that the processing is based on consent or a contract, and the processing is carried out by automated means.

When exercising your right to data portability, you have the right to have your personal data transmitted from one controller to another, where technically feasible.

Right to object (GDPR Article 21)

You have the right to object to processing your personal data, provided that the processing is based on the public interest or legitimate interests. The Data Controller will no longer have the right to process your personal data unless it can demonstrate compelling legitimate grounds for the processing that override the interests, rights and freedoms of the data subject, or unless it is necessary for the establishment, exercise or defence of legal claims. The Data Controller can continue processing your personal data also when necessary for the performance of a task carried out for reasons of the public interest.

Derogating from rights

In certain individual cases, derogations from the rights described here may be made on the basis of the GDPR and the Finnish Data Protection Act, insofar as the rights render impossible or seriously impair the achievement of scientific or historical research purposes or statistical purposes. The need for derogations will always be assessed on a case-by-case basis.

Right to lodge a complaint

You have the right to lodge a complaint with the Data Protection Ombudsman's Office if you think your personal data has been processed in violation of applicable data protection laws.

Contact details:

Data Protection Ombudsman's Office (Tietosuojavaltuutetun toimisto)
Address: Ratapihantie 9, 6th floor, 00520 Helsinki
Postal address: B.O. Box 800, 00521 Helsinki
Tel. (switchboard): 029 56 66700
Fax: 029 56 66735
E-mail: tietosuoja(at)om.fi