Participant Information Sheet

Study title:	**Impact of Charcot-Marie-Tooth Disease in the Auckland Region of NZ**		
Locality:	**Auckland**	Ethics committee ref.:	**TBC**
Lead investigator:	**Alice Theadom**	Contact phone number:	**0800 637738**

You are invited to take part in a study that is looking at how many people are affected by Charcot-Marie-Tooth Disease in Auckland. We would also like to find out how people are affected by this condition and their satisfaction with health and support services.

If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This information sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide, you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Please feel free to do this.

You will be asked if you agree to take part in this study before completing the questionnaire.

This information sheet is 6 pages long, including the consent form. Please make sure you have read and understood all the pages.

MUSCULAR DYSTROPHY Association of New Zealand Inc. Te Rōpū Mate Horokiwa o Aotearoa

AUT UNIVERSITY

WHAT IS THE PURPOSE OF THE STUDY?

We are a team of researchers who work in universities, hospitals and community organisations across New Zealand with an interest in supporting people with neuromuscular conditions.

The purpose of this study is to find out how many people are affected by Charcot-Marie-Tooth Disease in Auckland. We would also like to find out how peoples' everyday lives are affected and to identify where there are unmet need.

We hope that by finding out what support is currently available and what is needed, will help us to improve the support and treatment people receive. Even if you do not notice any effects from your condition, this is just as important for us to know as if you do.

This study is being funded by the Neuromuscular Research Foundation Trust and the Richdale Charitable Trust.

If you have any questions about the study please contact: [insert name of study manager]

Telephone: 0800 637738
Mobile: TBC
E mail: TBC

This study has been approved by the Health and Disability Ethics Committee reference: [To be inserted]

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

We are inviting everyone who has been diagnosed with Charcot-Marie-Tooth Disease to participate in this study (about 250 people). This will enable us to explore the services and supports people receive across the region. You have been identified as someone who may have been diagnosed with Charcot-Marie-Tooth Disease, or you represent a child or someone who is unable to take part themselves.

A researcher will talk to you about the study and you will have the opportunity to ask any questions you may have. If you would like to take part in this study, you will be asked to complete a questionnaire about how you find completing everyday activities, socializing, your quality of life, any symptoms you experience and the support that you receive. You can complete the questionnaire over the phone, online or on paper. We can also arrange for someone to visit you at home or another convenient location if you prefer.

The questionnaire should take about 30 minutes to complete. You will be able to have support people with you during the questionnaire and we can complete the questionnaire over several sessions if you prefer. Please just let us know.

We aim to finish collecting data for this study by the end of November 2016.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Taking part in this study will take some of your time and require you to answer a series of questions. There are no known risks caused by this study, however you may feel uncomfortable or embarrassed by some of the questions. You do not have to answer any questions you do not wish to do so.

Your own (or the person your repsent) usual medical care will not be affected in any way by your participation in this study, or if you decide to withdraw from the study at any stage. Your participation in this study will be stopped should you experience any harmful effects or if the doctor feels it is not in your best interests to continue. Similarly your doctor may at any time provide you with any other treatment he/she considers necessary.

We will also be in contact with your GP or neurologist to let them know about your participation in the study and to find out more about your diagnosis.

We will be talking with health care and service providers about the findings of the study to ensure the information collected is used to help improve services provide to people affected by this condition.

WHO PAYS FOR THE STUDY?

There should be no direct costs to you in taking part in this study.

A $20 food/fuel voucher will be provided to you after completion of the questionnaire in acknowledge of your contribution to this research.

The questionnaire can be completed over the phone, online or on paper. If for some reason you need to travel to complete the questionnaire, your mileage or costs (receipt/ticket required) will be reimbursed.

WHAT IF SOMETHING GOES WRONG?

It is unlikely that you will be at risk of harm from taking part in this study. **If something goes wrong, please contact the study manager as soon as possible on 0800 637738**

WHAT ARE MY RIGHTS?

Your participation is entirely voluntary and you will be able to withdraw from the study at any time without experiencing any disadvantage.

The study files and all other information that you provide will remain strictly confidential, unless information is revealed that indicates you or someone else is at risk. The answers to your questions will be stored separately to any document that has your name and contact details on.

No material that could personally identify you will be used in any reports or discussions about this study.

You will be able to access your information collected as part of the study if you wish to do so. If any information that may be of benefit to you emerges during the study we will contact you to let you know

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

Upon completion of the study your records will be stored for 16 years in a locked cabinet. The cabinet will be based at AUT University in Auckland by the lead investigator (Dr Alice Theadom). All computer records will be password protected. Any identifying information will not be shared outside of the research team without seeking your permission.

As there will be a lot of valuable information collected as part of this study, we would like to make anonymized data available to other international researchers on completion of the study. We will only share your anonymized data if you wish us to do so, otherwise your data will be deleted before any information is shared with other researchers.

After 16 years all electronic information will be deleted and paper forms will be shredded and destroyed in the university confidential waste.

After we have looked at all the data we will send you a summary of results. This will be in early 2017.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Study Manager [insert name]
Telephone number: 0800 637738
Email: [to be inserted]

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Please keep this for your information.
Thank you for interest in this study

Consent Form

If you need an INTERPRETER, please tell us.

Please read the following statements. You will need to confirm that you agree to these statements before completing the questionnaire.

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet dated 08/12/2015.

I have been given sufficient time to consider whether or not to participate in this study.

I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.

I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.

I consent to the research staff collecting and processing my information, including information about my health from medical records and health databases.

I consent to my GP or treating clinician being informed about my participation in the study and of any significant results obtained during the study.

I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.

I know who to contact if I have any questions about the study in general.