



## Participant Information and Consent Form

### Electrophysiological assessment of cryoneurotomy in spastic lower limbs

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#### INVITATION

You are being invited to participate in this research study due to your specific medical condition (lower limb spasticity), and because you are already accepted to have a specific treatment which is called cryoneurotomy. The study team is investigating the results of a specific test (lower limb muscles responses to mild electrical impulses) before and after this procedure and in compare to healthy participants.

#### YOUR PARTICIPATION IS VOLUNTARY

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled, or are presently receiving. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks and discomforts. Please ask the investigators of the study to explain any words and/or phrases that are not clear to you.

If you wish to participate in this study, you will be asked to sign the form at the end. Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

#### WHO IS CONDUCTING THE STUDY?

The study is being conducted by Principal Investigator Dr. Paul Winston at the multidisciplinary spasticity clinic at Victoria General Hospital (VGH), with help from members of the clinic. The study team is conducting the designed project to figure out muscles and nerves ability to conduct electrical impulses before and after cryoneurotomy, which is a part of your spasticity treatment protocol.

## **BACKGROUND**

Spasticity which can be defined as an abnormal increase in muscle tone, is a common condition, and can cause many complications and interfere with daily function. The spasticity multidisciplinary clinic at Victoria General Hospital has provided multiple treatments for spasticity including medications such as botulinum toxin injections or oral medications and procedures such as cryoneurotomy, which involves application of a low temperature probe to a nerve under ultrasound guidance for patients with problematic spasticity. The aim of this study is to compare nerve test results of persons who will have this treatment for spasticity and healthy people. This data will help us for better understanding of this procedure and its outcomes, which will consequently be used to improve future treatment options.

## **WHAT IS THE PURPOSE OF THE STUDY?**

The purpose of this study is to investigate possible changes in lower limb muscles electrical conduction before and after cryoneurotomy, which is already planned for you as a part of spasticity treatment. These parameters will be measured at specific time periods; before and at 1, 3 and 12 months after cryoneurotomy. The results will be compared to the other limb, and over time.

## **WHO CAN PARTICIPATE IN THIS STUDY?**

You may be able to participate in this study if you are:

- 1) An individual who will have cryoneurotomy as a part of your standard treatment for the foot position called the spastic equinovarus foot at the VGH spasticity multidisciplinary clinic.
- 2) An adult with the age between 18-70 years (male or female).
- 3) Able to attend testing sessions, comply with testing protocols and provide written informed consent.
- 4) Able to understand and complete study-related questionnaires (must be able to understand and speak English or have access to an appropriate interpreter as judged by the investigator).

## **WHO CANNOT PARTICIPATE IN THE STUDY?**

You cannot participate in this study if;

- 1) You have a history of previous nerve procedures such as chemical neurolysis with alcohol, cryoneurotomy, or surgery of the tibial nerve.
- 2) You have any other neurological pathology different from that responsible for the spasticity.

## **WHAT DOES THE STUDY INVOLVE?**

### **Overview of the Study**

The study will be conducted at the multidisciplinary spasticity clinic at Victoria General Hospital (VGH). You will be asked to participate in a brief test to measure your nerve electrical conduction, by applying a few mild electrical impulses and recording the responses by a small surface recorder.

### **Time Requirement**

You will be asked to do the test before the cryoneurotomy procedure, in the same day, and in 1, 3 and 12 months after the procedure, in the same days of your routine follow-ups. This testing session will last for approximately 15 minutes. During the testing session, both of your lower limbs will be tested.

### **If You Decide to Join this Study: Specific Procedures**

Descriptions of the procedures you can expect are described below:

1. Completion of this informed consent form.
2. Nerve conduction study: As part of the assessment, you will be asked to undergo an electrical test called “nerve conduction study”. We will be performing nerve conduction studies in your lower limbs. For each test, sticker electrodes will be applied over your leg muscles. A small electrical stimulator will be applied over your nerve by one of the study examiners. Brief, small electrical impulses will be applied over your nerve. The stimulator will slowly be turned up until the examiner sees the best response (about 10 to 15 electrical impulses). The electrical impulse may cause your leg to twitch. The same procedure will be done for your other limb, so we can compare them with each other.

3. Clinical information: The study team is hoping to compare your muscle testing results to some of your clinical information that is routinely collected during your visit(s) at the VGH multidisciplinary spasticity clinic. At the end of this consent form, you have the option of consenting for the study team to use some of that medical information for Electrophysiological assessment of cryoneurotomy in spastic lower limb

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research purposes. More information about how your medical information will be kept confidential is provided in the sections below.

### **WHAT ARE THE POSSIBLE HARMS AND DISCOMFORTS?**

Every effort will be made to ensure your safety, privacy and comfort. All study procedures are non-invasive, meaning that no drugs will be administered, and no blood will be drawn. The study procedures will be performed by members of spasticity clinic who have been trained to do that.

During nerve conduction studies, you may perceive some discomfort from the brief electrical impulses. As with any medical visit, you have the right to discontinue this testing at any time, if you feel it to be too uncomfortable. There are no lasting effects from nerve conduction studies.

### **WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?**

There is no direct benefit from your participation in the study; however, you and others may benefit from the knowledge generated from the study results.

### **WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?**

You will be informed in writing of any new information related to this study pertaining to your safety or anything that might influence your willingness to participate or continue. In this event you may be required to sign a new consent to indicate your willingness to continue to participate in the study.

### **WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?**

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, the study team will have a discussion with you about what will happen to the information that has already collected. You have the right to request the destruction of your information collected during the study, or you may choose to leave the study and allow the investigators to keep the information already collected about you until that point.

If you choose to have the data collected about you destroyed, this request will be respected to the extent possible. Please note however that there may be exceptions where the information will not be able to be withdrawn for example where the information is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please let a study team member know.

## **WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?**

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his designate and by representatives of UBC Clinical Research Ethics Board or Island Health Research Ethic Board for the purpose of monitoring the research. Furthermore, funding agencies and academic journals may require the release of study data, upon completion of the study. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. Only this number will be used on any research-related information collected about you during the course of this study, so that your identity [i.e. your name or any other information that could identify you] as a participant in this study will be kept confidential. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Information that contains your identity will remain only with the Dr. Winston and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be released unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected and also given you the right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to the Principal Investigator, Dr. Paul Winston.

## **WHAT HAPPENS IF SOMETHING GOES WRONG?**

By signing this form, you do not give up any of your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan.

## **WHAT WILL THE STUDY COST ME?**

There will be no cost to you for participating in the study.

## **DISPOSAL OF DATA:**

Your data from this study will be stored or disposed in the following manner:-

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-All completed case data forms will be retained for 5 years after study completion and then will be shredded.

-All your data will be kept in REDCap database on VIHA secure servers and will be destroyed as per Island Health REDCap protocols.

### **WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?**

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact the Principal Investigator, Dr. Paul Winston, via (250) 727-4221.

### **WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A RESEARCH SUBJECT?**

If you have any concerns or complains about your rights as a research subject and/or your experiences while participating in this study, contact Vancouver Island Health Authority Research Ethics board by e-mail at [researchethics@viha.ca](mailto:researchethics@viha.ca) or by phone at 250-519-6726. Please reference the study number [H20-02294] when calling so the Complaint Line staff can better assist you.

### **AFTER THE STUDY IS FINISHED**

Upon study completion, you will receive a comprehensive summary of your results, at your request.



