

**HREC Project Number:** HREC/16/RCHM/136

**Research Project Title:** Skin in Primary Lymphoedema

**Principal Researcher:** Ms Jane Phillips

**Version Number:** 3                      **Version Date:** 10/10/2017

Thank you for taking the time to read this **Participant Information Statement and Consent Form (Non-Lymphoedema Group)**. We would like to invite you to participate in a research project that is explained below.

This document is 5 pages long. Please make sure you have all the pages.

### **What is an Information Statement?**

These pages tell you about the research project. It explains to you clearly and openly all the steps and procedures of the project. The information is to help you to decide whether or not you would like to take part in the research. Please read this Information Statement carefully.

Before you decide to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

### **Important things you need to know**

- It is your choice whether or not you take part in the research. You do not have to agree if you do not want to
- If you decide you do not want to take part, it will not affect any treatment and care you get at <site >

If you would like to take part in the research project, please sign the consent form at the end of this information statement. By signing the consent form you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to taking part in the project

We will give you a copy of this information and consent form to keep.

## 1. What is the research project about?

Primary Lymphoedema is a rare condition which can occur in some children and adults. It is characterized by swelling of the limbs. We do not know how often it occurs in Australia. Currently, the standard treatment is to manage the risk of skin infection (that can happen with swelling) and reduce swelling with exercise, massage and compression. We do not know how the skin responds to compression or the best way to measure it.

This project aims to compare the skin of children, young people and adults aged between 3-40 years old, with and without lymphoedema, before and after a compression treatment is applied. This will provide information to help provide better management of lymphoedema and to help development of lymphoedema treatment guidelines for children.

It is hoped a total of 100 people will take part in this research.

## 2. Who is funding this research project?

The research is being conducted by Jane Phillips, as part of her PhD thesis, supported by Flinders University, South Australia. The project will take place at hospitals in Melbourne, Adelaide and Sydney.

## 3. Why am I being asked to be in this research project?

We are asking you because you do NOT have lymphoedema and are aged between 3 and 40 years of age.

## 4. What do I need to do in this research project?

We would like you to attend an appointment at <insert site name>. This appointment will take up to three hours to complete and will be organised at a time that suits you best. The appointment involves some assessment procedures and a compression treatment.

### Assessment Procedures

We will complete the following procedures before you are given the compression treatment:

- Ask you to visit the bathroom to empty your bladder before we complete any procedures
- Measure your height, weight and skin temperature
- Ask you to lie on a bed for 20 minutes to allow your body to adjust before taking some ultrasound pictures. We will cover your arm or leg with a towel, except while measuring
- Ask you some questions during this 20 minute adjustment time, including what is your preferred hand or leg
- Take ultrasound pictures of three different places on your arms or legs
- Following the ultrasound we will measure:
  1. Around your arm or leg using a tape measure
  2. How much the skin pushes back using a small machine called an Indurometer. This rests on your arm or leg and presses on the skin
  3. How stretchy your skin is by using an elasticity measure, which has a tiny cup that sucks on the skin
  4. How much moisture or water there is in the skin using a moisture meter

5. The amount of water in the arm or leg by doing a Bioimpedance test. This involves placing some sticky patches in different places on your arms and legs.

### Compression Treatment

We will massage (called manual lymphatic drainage) your armpits, the top of your legs and your trunk for approximately five minutes.

We will use an Intermittent Pneumatic Compression (IPC) device on your arm or leg. This treatment will take about 50 minutes to complete. This is a standard treatment for lymphoedema and is sometimes used to treat swelling related to sports injuries. An air-filled sleeve will apply waves of compression, in the same pattern as lymphatic massage is given. This will feel like gentle pressing on the leg or arm, starting at the top (thigh or arm) and gradually will include the hand or foot. The pressing is usually on for about 30 seconds, and then off for about 10 seconds. This will continue for about 40 minutes.

Following the compression treatment, we will repeat all the assessment procedures, as described above.

### Other important information

Before the appointment, please ensure you:

- Do not exercise for two hours
- Do not drink any caffeine (coffee or tea, sports drinks such as Red Bull or cola) for two hours
- Do not drink alcohol (if applicable) for 12 hours
- Do not apply moisturizer to your skin on the day of the appointment
- Wear light, loose-fitting clothing (such as t-shirt and tracksuit pants)
- Brings something to do while lying down, such as:
  - a book
  - an iPod with music to listen to
  - an iPad with a movie to watch.

## **5. Can I withdraw from the project?**

If you give your consent and change your mind, you can withdraw from the project. You do not need to tell us the reason why you want to stop being in the project. If you leave the project we will use any information already collected unless you tell us not to.

## **6. What are the possible benefits for me and other people in the future?**

There are no clear benefits for those without lymphoedema. We will give you a copy of your results with your individual measures before and after compression treatment, which you might find interesting.

We hope the information we get will benefit others in the future, by giving therapists more information for managing lymphoedema in both children and adults as well as helping to form treatment guidelines. This project will also provide information about the skin after compression for the general community, which will be of interest to therapists who use compression for travel or sporting purposes (recovery).

## **7. What are the possible risks, side-effects, discomforts and/or inconveniences?**

None of the measurements should hurt or cause discomfort. If you are uncomfortable, please tell us. You will have a towel to cover you and we will only uncover the areas near your ankle and knee or your arm where measurements are taken. You will be monitored during the compression treatment and a bell will be available for you to use if our attention is needed.

Measurement and treatment time will take 2 ½ -3 hours, during which time you will need to lie still for a few minutes at a time while measures are recorded. In between, while we set up each new measure, you will be able to wriggle. During the compression treatment, lying still is preferable, for approximately 40 minutes, which is when a game, book or other entertainment device could be useful. A bookstand which may assist in holding devices or books will be available.

(If you bring an electronic game, please consider if it can be played lying down, or, if you will need both hands available to play it with, as you might not have the use both arms all the time during measures and treatment. You can check this with us before you agree to participate.

Taking part in this study may cause some inconvenience as it needs approximately 2 ½ to 3 hours of your time. Appointments will be made for a time that suits you best, and out-of- business hours and weekends will be available wherever possible. **We will pay for parking costs at the <insert site name>**. You will be given a Hush Foundation CD as a thank you for taking part in the research project.

### **8. What will be done to make sure my information is confidential?**

Any information we collect that can identify you will be treated as confidential. It will be used only in this project, unless otherwise specified. We can disclose the information only with your permission, except as required by law.

All information will be stored securely in the School of Health Sciences at Flinders University. The results will be kept until the youngest participant is 25 years old. The research information may be destroyed or kept indefinitely in secure storage after this time. The only people who can access this information are the research team involved with this project and members of the Human Research Ethics Committee.

The stored information will be re-identifiable. This means that we will remove identifying information such as your name and give the information a special code number. Only the research team can match your name to your code number, if it is necessary to do so.

In accordance with relevant Australian and/or **<insert applicable state name>** privacy and other relevant laws, you have the right to access and correct the information we collect and store about you. Please contact us if you would like to access this information.

At the end of the study, results may be presented at conferences or published in medical journals. This will be done in such a way that you cannot be identified. The results of this research will be used by Jane Phillips as part of her PhD thesis requirements.

### **9. Will we be informed of the results when the research project is finished?**

We will send you a summary of group results at the end of the study. The summary will be of the whole group of research study participants, not individual results.

### **10. Who should I contact for more information?**

If you would like more information about the project or if you need to speak to a member of the research team in an emergency please contact:

**Name:** Jane Phillips

**Contact telephone:** 0418 104 690

**Email:** [jane.phillips@flinders.edu.au](mailto:jane.phillips@flinders.edu.au)

If you have any concerns and/or complaints about the project, the way it is being conducted or your rights as a research participant, and would like to speak to someone independent of the project, please contact: Director, Research Ethics & Governance, The Royal Children's Hospital Melbourne on telephone: (03) 9345 5044.

**CONSENT FORM**

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- I have read, or had read to me in my first language, the information statement version listed above and I understand its contents.
- I believe I understand the purpose, extent and possible risks of my involvement in this project.
- I voluntarily consent to take part in this research project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that this project has been approved by The Royal Children’s Hospital Melbourne Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007) - including all updates.
- I understand I will receive a copy of this Information Statement and Consent Form.

\_\_\_\_\_  
Participant Name                      Participant Signature                      Date

Declaration by researcher: I have explained the project to the participant who has signed above, and believe that they understand the purpose, extent and possible risks of their involvement in this project.

\_\_\_\_\_  
Research Team Member Name                      Research Team Member Signature                      Date

Note: All parties signing the Consent Form must date their own signature.