Participant Information and Consent Form

Study title: Imaging the lymphatic vessels in the arm using advanced devices

Formal study title: Indocyanine Green (ICG) lymphography and optical coherence tomography (OCT) imaging of the lymphatic system

Principal Investigator: Dr Hayley Reynolds

Contact email address: Hayley.Reynolds@auckland.ac.nz

Ethics committee reference: 2025 FULL 21518

Invitation

You are invited to take part in a research study. This Participant Information document explains why we are doing the study and what it involves. It also describes the possible benefits, risks, and what happens after the study ends. We will go through this information with you and answer any questions you may have. You will need to take at least 24 hours to consider whether you would like to take part in this study. You can take longer if you need to. . Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information document and the Consent Form to keep.

This document is 9 pages long, including the Consent Form. Please make sure you have read and understood all the pages before deciding whether to participate.

Is Participation Voluntary and Can I Withdraw from This Study?

Yes. Taking part in this study is completely voluntary. You can choose not to participate or withdraw at any time, even after the imaging session has started, without giving a reason and without any consequences. If you decide to withdraw, you can also choose whether we keep or delete any data already collected.

What Is the Purpose of the Study?

This study aims to collect imaging data of lymphatic vessels in the arms of healthy volunteers. Lymphatic vessels are tiny tubes that carry a clear fluid called lymph. This fluid helps remove waste and move immune cells around the body. By collecting imaging data of lymphatic vessels in the arm we aim to better understand lymphoedema, which is a

condition that causes swelling when fluid cannot drain properly through the lymphatic system. It affects about 250 million people worldwide and often occurs after cancer treatments such as surgery or radiation, and is particularly common in breast cancer patients. Lymphoedema can cause physical changes, discomfort, and emotional distress. Currently, doctors cannot predict who will develop it or how severe it will become.

Our goal is to change this by creating detailed computer models of the lymphatic system. These models aim to help explain how lymphoedema develops and may lead to ways of predicting risk and improving prevention or treatment. By taking part, you will help us gather the imaging data needed to accurately build these models. This research could improve quality of life for people affected by lymphoedema in the future.

Who Can Take Part in the Study?

Healthy adults aged 25 to 70 years who can read and understand English can join this study. You need to understand what the study involves, be willing to follow the procedures, and be able to give written consent to take part.

You cannot take part if you have any of the following:

- Lymphoedema of the upper limb
- Previous surgery of the upper limb
- Any medical condition that may result in swelling;
    - Uncontrolled congestive cardiac failure,
    - Arteriovenous haemodialysis,
    - Current infection or cellulitis.
- Be pregnant or currently breast feeding.
- Have a known over-active thyroid or known benign thyroid tumour
- Have a known anaphylaxis to sodium iodide, iodine, or shellfish
- Have a history of allergic skin reactions, contact dermatitis, or hypersensitivity to topical agents or ointments (including azo dyes or tartrazine)
- Have a history of allergic reactions to ICG
- Have evidence of active cancer
- Have a pacemaker or internal defibrillator

What Will Participation Involve?

If you agree to take part, you will attend one appointment at the Auckland Bioengineering Institute that will take about 1.5 hours. When you arrive, a member of the research team will explain the study again and answer any questions you have. You will then be asked to sign a consent form. Next, you will complete a short survey about your age, sex, and general

health. We will measure your height, weight, and the size of your arm using a tape measure. Small marks may be made on your arm to guide imaging, and we will take photos of your arm (not your face) for reference.

After this, we will perform two imaging procedures. The first is called Optical Coherence Tomography (OCT), which uses light to take detailed pictures of the tissue under your skin. This is completely non-invasive and does not involve radiation. A small hand-held scanner will be gently placed on different spots on your arm while you sit or lie comfortably with your arm supported. Your skin may be cleaned with an alcohol wipe, and if needed, a colouring agent (called tartrazine) may be applied to improve image quality. This part will take about 30 minutes.

The second procedure is called Indocyanine Green (ICG) lymphography, which shows how fluid moves through the lymphatic vessels in your arm. A trained medical professional will give four very small injections of ICG dye into your hand and wrist. Before each injection, a cooling device will be applied for a few seconds to numb the skin and reduce discomfort. After the injections, two special cameras will take images of your arm to track the dye as it moves through your lymphatic system. You will rest your arm in a comfortable position while the cameras capture images. This part will take about 45 minutes.

When all imaging is complete, any marks or colouring agents will be cleaned off your skin. You will receive a small koha as a thank you for your time. If you wish, you can request a copy of some images which will be send within 1 month, and a summary of the study results which you will receive by February 2027. All procedures are designed to be safe and cause minimal discomfort, and you can stop or withdraw from the study at any time without giving a reason.

What Are the Possible Risks of This Study?

The procedures in this study are considered very low risk. OCT imaging is non-invasive and uses light only, so it does not involve radiation or injections. You may feel mild warmth or slight pressure from the scanner on your skin. For ICG lymphography, we will inject a small amount of dye under the skin at four spots on your hand and wrist. This dye has been used safely for many years. There is a very small chance of an allergic reaction, such as mild itching where the dye was injected. We will ask about any allergies beforehand and have antihistamines available if needed. Before each injection, a cooling device will be used for a few seconds to numb the skin; this carries a very small risk of cold irritation, which we minimize by strict temperature control. If a colouring agent (tartrazine) is applied to improve image quality, there is a small chance of skin irritation, so we will test a tiny patch first and wash it off immediately if any reaction occurs. All imaging devices meet safety

standards, and protective eyewear will be provided during imaging. You can stop the procedure at any time if you feel uncomfortable.

What Are the Possible Benefits of This Study?

There is no direct health benefit to you from taking part in this study. However, your participation will help researchers better understand how the lymphatic system works and why conditions like lymphoedema develop after cancer treatment. This knowledge could lead to improved ways to predict, prevent, and manage lymphoedema in the future. You may also find it interesting to see images of your own lymphatic system, and you can request a copy of some images and a summary of the study results if you wish.

Koha

You will receive a $50 koha to thank you for your time and contribution to this research.

What If Something Goes Wrong?

This study is very low risk, but if you experience any problems during or after the session - such as skin irritation, discomfort, or an allergic reaction - please tell a member of the research team immediately. A trained medical professional will be present during the imaging session and can provide first aid if needed. If you have an allergic reaction to the dye or colouring agent, we will stop the procedure and provide appropriate care, such as antihistamines. You will also be given the contact details of the Principal Investigator and the attending medical professional so you can report any concerns after you leave. Any unexpected reactions will be documented and reported to the Centre for Adverse Reactions Monitoring (CARM) and the ethics committee. If imaging shows something unusual that might be important for your health, we will let you know and advise you to see your doctor. You can withdraw from the study at any time without giving a reason.

What Will Happen to My Information?

Your information will be kept confidential and stored securely. Your name will not appear on any data; instead, you will be given a study ID number so your information is de-identified. We will keep paper copies of your consent form in a locked drawer. Electronic data will be stored securely on University of Auckland systems. Only the research team will have access to your data. The results may be published or presented, but nothing that identifies you will be included. With your permission, your de-identified data may also be used for future research related to lymphatic imaging and modelling. Results from this study

will not be made available to participants of any future research using data collected in this study.

What Happens After the Study or If I Change My Mind?

You can withdraw from the study at any time, even after the imaging session, without giving a reason. If you withdraw, we will stop collecting data immediately. You can choose whether we keep or delete any data already collected. After the study is complete, your data will remain securely stored for research purposes unless you request its removal.

Can I Find Out The Results of the Study?

Yes. You can request a copy of some of your images and a summary of the study results. Because the imaging files are very large, we will provide selected images or a short video rather than the full dataset. This will be provided to you within 1 month of your imaging study. You can also ask for a summary of the overall findings once the research is complete, which will be in February 2027.

What Are the Māori Cultural Considerations?

In partnership with Iwi United Engaged (IUE), we are implementing a Kaupapa Māori community engagement approach to ensure Māori volunteers are recognised as research partners and that this study is meaningful and responsive to Māori affected by lymphoedema. We acknowledge the cultural significance of health research for Māori and are committed to upholding the principles of Te Tiriti o Waitangi, including tino rangatiratanga (self-determination), partnership, equity, options, and active protection.

This means we respect participants' rights to make informed decisions about participation (tino rangatiratanga), work collaboratively with Māori communities and IUE throughout the research process (partnership), actively address inequities in health outcomes (equity), and ensure culturally appropriate processes and access to Māori-led support (options).

Active protection includes safeguarding Māori cultural values, wellbeing, and rights in research. This extends to upholding Māori data sovereignty — ensuring that data relating to Māori is collected, stored, analysed, and shared in ways that respect Māori authority, governance, and control over their information. We are committed to transparent data management processes and to protecting the integrity and appropriate use of Māori data.

We have included wording to ensure participants are aware they may share any cultural preferences (e.g., karakia), request whānau or support person presence, and connect with a Māori member of the IUE research team. Participation remains entirely voluntary, and cultural needs can be discussed at any stage of the research process.

Who Is Funding the Study?

This study is funded by a Royal Society of New Zealand Marsden grant (MFP-UOA2315). The funding supports the development of imaging devices and data analysis at the Auckland Bioengineering Institute and the Department of Physics at the University of Auckland

Who Has Approved the Study?

The study has been reviewed and approved by the Health and Disability Ethics Committee (HDEC) in accordance with national guidelines for ethical research.

Who Do I Contact for More Information or If I Have Concerns?

If you have any questions or concerns, you can contact the Principal Investigator:

Dr Hayley Reynolds

Auckland Bioengineering Institute

University of Auckland

Email: Hayley.Reynolds@auckland.ac.nz

Phone: 022 5161 584

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@advocacy.org.nz
Website:	https://www.advocacy.org.nz/

If you have concerns about your rights as a participant, you can contact the Health and Disability Ethics Committee.

Email:	hdecs@health.govt.nz
Phone:	0800 4 ETHICS (0800 438 442)

Consent Form

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Principal Investigator: Dr Hayley Reynolds

I have read and I understand the Participant Information Sheet.	
I have been given enough time to consider whether or not to take part.	
I have had the opportunity to ask questions and discuss the study with the research team, and I am satisfied with the answers I have been given.	
I understand that taking part in this study is voluntary (my choice) and I may withdraw at any time without giving a reason and without any consequences.	
I consent to the research team collecting and processing my information, including health information, for the purposes of this study.	
I understand that my information will be de-identified and stored securely, and that no material which could identify me will be used in any reports or publications.	
I consent to my de-identified data being used for future research related to lymphatic imaging and modelling.	
If I decide to withdraw from the study, I agree that the information collected about me up to the point of withdrawal may continue to be used in a de-identified form.	

I understand that a trained medical professional will perform the ICG injections and that I can stop the procedure at any time.	
I understand the possible risks of the study and the steps taken to minimise them.	
I know who to contact if I have any questions or concerns about the study or my rights as a participant.	
I consent to the application of tartrazine (a colouring agent) to my skin to improve image quality.	☐ Yes ☐ No
I wish to receive a summary of the results from the study.	☐ Yes ☐ No

Declaration by participant:

I hereby consent to take part in this study.

Name: _____

Signature: _____ Date: _____

Withdrawal of Consent Form

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I wish to withdraw my consent to participate in the above study.

Please indicate your preference:

☐ I do not want any further contact from the research team.

☐ I request that my data collected so far be removed and not used in the study analysis.

☐ I understand that if my data has already been de-identified and included in aggregated analyses, it may not be possible to remove it.

Name: _____

Signature: _____ Date: _____