Participant Information Sheet/Consent Form

Project Title: *The feasibility of an online Yoga Sequence for Breast Cancer-related Lymphoedema (BCRL)*

PART 1 What does my participation involve?

1. Introduction

You are invited to participate in a research study exploring an online yoga program for people with breast cancer related lymphoedema.

This Participant Information Sheet/Consent Form tells you about the research project. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2. What is the purpose of this research?

Some research has explored the effective of online yoga for different symptoms people with cancer may experience. Several small studies have been completed demonstrating a specialised yoga sequence for lymphoedema when compared to usual care may result in improvements in arm volume (circumference), range of motion and quality of life. But there have been no studies undertaken to examine an online yoga program.

This research has been initiated by the study Principal Investigator, Dr Suzanne Grant and the Yoga Therapist, Margery Hellman. It is being undertaken by the Chris O'Brien Lifehouse and Western Sydney University to better understand whether this type of program is acceptable to people with breast cancer related lymphoedema and if there are any changes in the arm, coping and quality of life at the end of the program compared to the start. The yoga intervention is funded by Dry July.

3. What does participation in this research involve?

The initial appointment will be conducted face to face, while the group yoga classes will be conducted online via the ZOOM video conferencing platform. For your security you will be provided with a password to access the class. If you agree to participate in this study, you will be asked to attend a face-to-face appointment. You will have the opportunity to discuss your eligibility to participate in this clinical trial. To assess your eligibility, you will be asked to read and voluntarily provide written informed consent.

Once informed consent is given, the research officer will ask about your demographic information, and complete an exercise questionnaire to ensure you can safely undertake the yoga program. If you are eligible, you will be enrolled in the study and be asked to complete four questionnaires about your current symptoms and quality of life.

The research officer will then take a measure of your arm volume, and assess your range of movement. We will also use a bioimpedance spectroscopy (BIS – SOZO). This is a non-invasive technique to measure extracellular fluid which

involves passing an extremely small electric current through the body and measuring the impedance (resistance) to the flow of this current.

We will follow all hospital COVID safe protocols during this face to face visit. This will include check-in at the hospital front desk, answering questions about symptoms and if you have been in any COVID hotspots. We will also ask you to wear a mask during this visit. If you do not have one, a mask will be provided at the front desk check-in. We will also follow COVID hospital guidelines for handwashing, disinfecting all equipment used during the visit and social distancing.

You will then have an individual face-to-face yoga session with the yoga therapist to take you through postures that will be used in the study, and to ensure that you understand how to use the ZOOM online technology at home. If you do not have access to ZOOM you will not be able participate in this study.

The course and assessments are provided free of charge, and participation in the study will cost you nothing, nor will you be paid.

4. What do I have to do?

The initial face-to-face screening and enrolment will take approximately 30 minutes, and you will spend an additional one hour participating in an individual yoga session with the yoga therapist.

After this initial enrolment and yoga session, you will be required to attend a weekly group yoga class online for 12 weeks. There will be a maximum of 8 participants in each class. We will also provide you with a video with a short yoga sequence (15 mins) for you to do on your own at home every day. This will include a total 11 hours of yoga over 12 weeks, along with the daily self-practice.

At the completion of the study you will be asked to attend a final face-to-face appointment where we will again take your arm volume measure, range of movement and a bioimpedance measure. We will also ask you complete five questionnaires and provide some written feedback on the program.

There will be up to 40 women who will be recruited into this study overall.

5. What benefits will I, and/or the broader community, receive for participating?

While we intend that this research study furthers medical knowledge and may improve treatment by better understanding the use of yoga for breast cancer related lymphoedema. There is potential that your participation may improve your lymphoedema, and your quality of life.

6. Will the study involve any risk or discomfort for me?

Yoga interventions are generally considered to be safe, with no known risk of physical or psychological harm. The yoga interventions will be conducted by certified yoga instructor. If any coincidental worsening or exacerbation of symptoms is evident, the yoga practices can be modified, so that the person does not experience distress or discomfort. Yoga postures included in this study are gentle in nature.

Yoga generally has low rates of adverse events, and occurrences of these are not anticipated in this study. An adverse events record form will be used to record any unexpected signs, symptoms or feelings of distress or discomfort during the trial period. All reported adverse events that occur between consent and the last visit for the study will be recorded in detail. If any symptoms do develop after consent and during the trial, you will be instructed to contact the Clinical Trial Officer. In the case of an adverse event, the Investigator may recommend that you seek medical advice from a general practitioner (GP) or other health professional. Participants with adverse events present at their last visit will be followed-up until resolution of the event.

7. How do you intend to publish or disseminate the results?

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified, such as tables and graphs showing the overall information. At completion of the study a summary of results will be made available to participants on request.

8. Will the data and information that I have provided be disposed of?

You will be allocated a study code after you sign the Participant Information Sheet and Consent Form. This code will replace all information that could potentially identify you such as your address, date of birth and medical record number. The key linking this code to you will be held securely by the Coordinating Principal Investigator. During the study information collected from you for the purposes of the study will be coded and will not contain information that can identify you. Study information will be stored securely on a cloud based Information Technology platform at Western Sydney University. Information will also be stored on the Chris O'Brien Lifehouse secure servers. No identifiable information will be transferred off site. Your signed Consent form will not leave the study site and will be stored securely. Once the study is completed all coded study information will be transferred onto secure Western Sydney University servers to store for five years. . In accordance with the Australian privacy and other relevant laws, you have the right to request access to your information that we have collected and stored by the research team. The data and information you have provided will be securely held and disposed of in accordance with the Australian privacy and other relevant laws.

Please be assured that only the researchers will have access to the raw data you provide. Information collected about you will be kept for future use for research studies currently unknown and may be shared with National and International research collaborators however ethical approval will be obtained prior to their use.

9. Can I withdraw from the study?

Participation is entirely voluntary, and you are not obliged to be involved. If you do choose to participate you can withdraw at any time, you can advise us that you do not consent for us to use the data we collected up until your withdrawal. We will only use the information that you give consent for us to use. Whatever your decision, it will not affect your treatment or your relationship with the research or medical staff.

Ethics Approval

This study has been approved by the St Vincent's Hospital Human Research Ethics Committee (approval number 2020/ETH02315) and the Western Sydney University Human Research Ethics Committee (approval number (H14194).

What if I require further information?

Chris O'Brien Lifehouse

Please contact *Dr Suzanne Grant* should you wish further information.

Dr Suzanne Grant, Email: suzanne.grant@lh.org.au

Phone: 0419126209

Western Sydney University

Please contact *Ms Maria Gonzalez* should you wish further information.

Ms Maria Gonzalez, Email: maria.gonzalez2@westernsydney.edu.au

Phone: 0404127638

What if I have a complaint?

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and Research Officer details

Reviewing HREC name	St Vincent's Hospital HREC
Position	Research Officer
Telephone	02 8382 4960
Email	SVHS.Research@svha.org.au

Reviewing HREC name	Western Sydney University HREC
Position	Research Officer
Telephone	02 4736 0229
Email	humanethics@westernsydney.edu.au

Local Research Office/Complaints contact

Position	Research Governance Manager Chris O'Brien Lifehouse
Telephone	02 8514 0410
Email	researchgovernance@lh.org.au

Position	Ethics Committee, Research Engagement, Development and Innovation (REDI) Western Sydney University
Telephone	02 4736 0229
Email	humanethics@westernsydney.edu.au

PARTICIPANT CONSENT FORM

Project Title: *The Feasibility of an online Yoga Sequence for Breast Cancer-related Lymphoedema*

Declaration by Participant

I hereby consent to participate in the above named research project.

I acknowledge that:

- I have read the participant information sheet (or where appropriate, have had it read to me) and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s
- The procedures required for the project and the time involved have been explained to me, and any questions I have about the project have been answered to my satisfaction.

I consent for my data and information provided to be used for this project.

I agree for my information (data) to be retained for use in future projects:

- ☐ **YES**
- ☐ **NO**

I agree for my deidentified information collected during the study to be shared with collaborators nationally and internationally. I understand that before they can use my information, they must seek additional ethics approval.

- ☐ **YES**
- ☐ **NO**

I understand that my involvement is confidential and that the information gained during the study may be published but no information about me will be used in any way that reveals my identity.

I understand that I can withdraw from the study at any time without affecting my relationship with the researcher/s, and any organisations involved, now or in the future.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print)

_____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Name of Study Doctor/Senior Researcher† (please print)

_____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning the research project.

Note: All parties signing the consent section must date their own signature.