The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	**Project Limb Rescue: A pilot study evaluating the feasibility of transcutaneous sensors for the detection of cancer-related lymphedema**
Principal Investigator:	**Carlo M. Contreras, MD**
Sponsor:	The Ohio State University

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study
The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

Millions of cancer survivors have lymphedema, which is long-term arm swelling after completing their cancer therapy. This study is being done to find out if it is possible to use our new, adhesive-based sensors (pads that stick on your skin) to detect lymphedema, and to develop a way for patients to check for lymphedema at home.

If you participate in this study, you will not receive any treatment for any medical condition, but you may be pleased to know that you could be helping the study team find a new way to help people who suffer from lymphedema.

1. Why is this study being done?

For many patients, lymphedema (long-term arm swelling) is painful, unsightly, and weakening. The early signs of lymphedema are hard to see, and sometimes it is only diagnosed by hospital equipment at larger centers. Treating lymphedema early is usually more successful than trying to treat in later stages. The goal of this study is to use new, adhesive-based sensors (pads that stick on your skin) to detect lymphedema, and to develop a way for patients to check for lymphedema at home. This study will assist in distinguishing participants with lymphedema in comparison to participants without lymphedema at rest by using a combination of photoplethysmography (PPG) and bioimpedance (BI). Photoplethysmography is an optical technique that can be used to detect blood volume changes in tissue. Bioimpedance evaluates how tissue responds to an externally applied electrical current.

2. How many people will take part in this study?

A total of 70 people will take part in this study; 35 people who have lymphedema, and 35 people who do not have lymphedema.

3. What will happen if I take part in this study?

Those who participate in this study will complete a few steps:

- Series of questions (through a website or by telephone) to check and see if you are a good fit for the study.
- One in-person visit to our study facility which is located on The Ohio State University medical center campus. This one-time in-person visit will last 2.5 hours and will include:
    - Complete additional medical questions to see if and how cancer and/or arm swelling may have impacted your life.
    - If used, remove your arm compression garment during the in-person study visit.
    - Measurements of your arms with a flexible tape measure to see if there are size differences.
    - Step onto a device that is very similar to a weigh scale to tell how much fluid is in your body.
    - Use sensors that sit on top of the skin of both arms to try and look for differences in swelling between your right and left arms. We will look for swelling by measuring a type of fluid called “interstitial” fluid. This is the fluid within your tissues, but outside your blood vessels. These sensors will be removed at the end of the in-person visit.
        - One type of sensor that uses photoplethysmography will touch your skin very much like a watch touches your skin around your wrist. You will be asked to sit for 15 minutes. This “watch-like” sensor shines a type of light wave towards your skin and then measures how much of the light wave bounces back into the sensor that sits on top of your skin.

- The other type of sensor that uses bioimpedance will be placed on your skin with medical-type adhesive, very similar to what are used for ECG (electrocardiogram) heart rhythm tests. A few small adhesive sensors will be placed on the skin of your arm and shoulder and these measure natural electrical signals that our bodies naturally make. We are specifically looking to see if there is a difference in these electrical signals based on the amount of swelling from one arm to the other.

- Next, you will be asked to pedal on a stationary bicycle (a bicycle that does not move) while wearing the sensors for about 5 minutes.
- Following, you will then sit again for 5 minutes.
- Once finished, we will remove all the skin sensors.

4. How long will I be in the study?

You will spend about 30 minutes answering medical questions to make sure you are a good fit for this study. Then you will have one in-person visit in our study facility that will last around 2.5 hours.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

Participating in this study is unlikely to result in any serious side effects. Since you will be asked to pedal on a seated bicycle during the in-person visit, it is possible that you might feel winded or tired after pedaling for approximately 5 minutes. A clinical member of the research team will be present for the entire visit in case you do need any assistance. Medical-grade adhesives are used which lowers but does not eliminate the risk of skin irritation where the sensors touch the skin. You may also experience temporary increase in lymphedema if a compression garment is removed for this study. This study does not involve taking any medications or getting any blood or urine samples.

7. What benefits can I expect from being in the study?

If you participate, you will not receive any treatment for any medical condition, but you may be pleased to know that you could be helping the study team find a new way to help people who suffer from lymphedema.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There are no costs to you by participating. You will not need to pay for parking for the in-person study visit; this will be covered by the study.

10. Will I be paid for taking part in this study?

When you complete the in-person study visit you will be compensated with one $75 electronic Amazon gift card. By law, payments to participants are considered taxable income. While you will not be reimbursed for your travel, you will be provided with a parking voucher for use when you come for your in-person visit.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information (and bio-specimens) be used or shared for future research?

Yes, it may be used or shared with other researchers without your additional informed consent.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If we find information that significantly impacts your health, we will share it with you. Relevant information will be shared with you by your physician at a clinic visit.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Diaries and questionnaires
- Records about the study device

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record

IV.IV Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX.IX Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For study questions, concerns, or complaints, to withdraw consent and HIPAA authorization, or if you feel you have been harmed as a result of study participation, you may contact Dr. Carlo Contreras at 614-366-3681.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact 614-293-6482 or 614-293-7672.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Carlo Contreras at 614-366-3681.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
	AM/PM
Relationship to the participant	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time