Protocol Title:
Evaluation of the validity of BIS as a tool for quantification of lymphedema through comparison with perometry and self-report

DF/HCC Principal Research Investigator / Institution:
Alphonse G. Taghian, MD, PhD / MGH

A. INTRODUCTION

We are inviting you to take part in a research study. Research is a way of gaining new knowledge. A person who participates in a research study is called a "participant." This research study is evaluating the use of a special device called Bioimpedance Spectroscopy to screen for lymphedema in patients who have breast cancer.

It is expected that about 270 people will take part in this research study.

An institution that is supporting a research study either by giving money or supplying something that is important for the research is called the "sponsor." The sponsor of this protocol is the National Institutes of Health (NIH) and is providing funding for the research study.

Some research studies are supported in some way by an outside organization. The National Institutes of Health (NIH) is supporting this research study by providing funding for the research study

This research consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of the research study, alternatives to participation, and your rights as a research participant. The decision to participate is yours. If you decide to participate, please sign and date at the end of the form. We will give you a copy so that you can refer to it while you are involved in this research study.

If you decide to participate in this research study, certain questions will be asked of you or certain tests will be taken to see if you are eligible to be in the research study. These tests are called screening tests. The research study has certain requirements that must be met. If the screening tests show that you can be in the research study, you will be able to start on the study.

DFCI Protocol Number:	11-325	Approved Date (DFCI IRB Approval):	03/04/2019
Date Posted for Use:	03/04/2019	Expiration Date (Invalid for use on or after):	03/04/2020
Version Date (OnCore):	03/04/2019	Content Last Revised with OHRS Review:	AM #12

If the tests show that you cannot be in the research study, you will not be able to participate in this research study.

We encourage you to take some time to think this over and to discuss it with other people and your doctor, and to ask questions now and at any time in the future.

B. WHY IS THIS RESEARCH STUDY BEING DONE?

Women who have been treated for breast cancer may be at risk for lymphedema, or arm swelling. Currently, it is not known what the best method for identifying and monitoring lymphedema is. Lymphedema can be detected by measuring changes in arm volume using a machine called a Perometer, or through reported symptoms of swelling and heaviness. Another method uses a device called Bioimpedance Spectroscopy to monitor changes in the amount of fluid in your arms.

The purpose of this study is to determine whether measuring the fluid in your arms using Bioimpedance Spectroscopy is as effective at detecting and monitoring lymphedema as measurements with the Perometer. We will also evaluate any symptoms you may experience in your arms during and after treatment for breast cancer with a questionnaire.

C. WHAT OTHER OPTIONS ARE THERE?

Taking part in this research study is voluntary. Instead of being in this research study, you have the following options:

- Decide not to participate in this research study.
- Continue with screening for lymphedema using only the Perometer.
- No screening for lymphedema.
- Participate in another research study.

D. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Before the research starts (screening): After signing this consent form, you will be asked to answer some questions or undergo some screening tests or procedures to find out if you can be in the research study. These tests and procedures are likely to be part of regular cancer care and may be done even if it

DFCI Protocol Number:	11-325	Approved Date (DFCI IRB Approval):	03/04/2019
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Version Date (OnCore):	03/04/2019	Content Last Revised with OHRS Review:	AM #12

turns out that you do not take part in the research study. IF you have had some of these tests of procedures recently, they may or may not have to be repeated.

- **A medical history**, including questions about your health, current medications, and any allergies
- **Physical exam** including height and weight.
- **Vital signs**, including blood pressure, pulse, body temperature, and respiratory rate.
- **Arm volume measurement** (Perometer Measurement) for both arms. For this procedure, we will use a harmless infrared light to scan each of your arms. The images created by the scan will tell us the size and volume of your arm. You will feel no pain or discomfort from this procedure. This will not take more than 5 minutes.

If these tests show that you are eligible to participate in the research study, you will be eligible to participate in the research study. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

After the screening procedures confirm that you are eligible to participate in the research study:

During the study, whenever you have an arm volume measurement using the Perometer, we will also measure the fluid in your arms using Bioimpedance Spectroscopy. These measurements are made by passing a harmless electrical signal of very low strength through your body to determine the difference in the amount of fluid in each arm. The test is simple and painless, and takes about 3 minutes. In addition, whenever you have an arm measurement, you will be asked to complete a questionnaire. While completing the questionnaire, you can skip any questions you do not wish to answer. The questionnaires will take about 10 minutes to complete. Arm measurements with the Perometer and Bioimpedance Spectroscopy and completion of the questionnaire will occur every 4-12 months, for a period of 24 months following completion your breast cancer treatment, when you are at MGH for regular medical visits. Following this 24 month time period, we will measure you with the BIS device at least once every 10-20 months.

E. HOW LONG WILL I BE IN THIS RESEARCH STUDY?

You will be in this research study for about five years. This research will be done throughout your treatment for breast cancer and in the first 5 years after your treatment. As part of this study you will complete arm measurements with the Perometer and Bioimpedance Spectroscopy and questionnaires.

DFCI Protocol Number:	11-325	Approved Date (DFCI IRB Approval):	03/04/2019
Date Posted for Use:	03/04/2019	Expiration Date (Invalid for use on or after):	03/04/2020
Version Date (OnCore):	03/04/2019	Content Last Revised with OHRS Review:	AM #12

The research Investigator may decide to take you off the research study for many reasons including if:

- It is considered to be in your best interest
- The study procedures are found to be unsafe or ineffective
- There is any problem with following study procedures
- There are any problems with research funding
- Or for any other reason

If you are removed from the research study, the research Investigator will explain to you why you were removed.

In addition, you can stop participating in the research study at any time.

F. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?

There are risks to taking part in any research study. During the research study, you will be provided with any new information that may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

The questionnaires used in this study may be upsetting. If you find the questionnaires upsetting, you may speak with the research doctor or ask to be referred for additional emotional support.

G. WHAT ARE THE BENEFITS OF THE RESEARCH STUDY?

Taking part in this research study may or may not benefit you. We hope the information learned from this research study will provide more information about the best methods for detecting and monitoring lymphedema in breast cancer patients.

H. CAN I STOP BEING IN THE RESEARCH STUDY AND WHAT ARE MY RIGHTS?

You have the right to choose not to sign this form. If you decide not to sign this form, you cannot participate in this research study.

You can stop being in the research study at any time. Leaving the research study will not affect your medical care. You can still get your medical care from your hospital or Investigator.

DFCI Protocol Number:	11-325	Approved Date (DFCI IRB Approval):	03/04/2019
Date Posted for Use:	03/04/2019	Expiration Date (Invalid for use on or after):	03/04/2020
Version Date (OnCore):	03/04/2019	Content Last Revised with OHRS Review:	AM #12

If you choose to not participate, or if you are not eligible to participate, or if you withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

I. WHAT ARE THE COSTS?

Taking part in this research study will not lead to added costs to you or your insurance company.

You will not be charged for the following that are part of this research study:

- Perometer Measurements
- Bioimpedance Spectroscopy Measurements

You or your insurance company will be charged for other portions of your care during this research study that is considered standard care. You may be responsible for co-payments and deductibles that are standard for your insurance coverage.

If you have questions about your insurance coverage, or the items you might be required to pay for, please call financial services for information. The contact information for financial services:

- Massachusetts General Hospital: (617) 726-2191

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below.

http://www.cancer.gov/clinicaltrials/learning/insurance-coverage

J. WHAT HAPPENS IF I AM INJURED OR SICK BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

DFCI Protocol Number:	11-325	Approved Date (DFCI IRB Approval):	03/04/2019
Date Posted for Use:	03/04/2019	Expiration Date (Invalid for use on or after):	03/04/2020
Version Date (OnCore):	03/04/2019	Content Last Revised with OHRS Review:	AM #12

Providing your care does not mean that DF/HCC or the research Investigators are at fault, or that there was wrongdoing. There are no plans for DF/HCC to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research Investigator's name and phone number are listed in this consent form.

K. WHAT ABOUT CONFIDENTIALITY?

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

Medical information created by this research study may become part of your hospital medical record. Information that does not become part of your medical record will be stored in your study file. It may also become part of a DF/HCC research database called CORIS.

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

The results of this research study may be published. You will not be identified in publications without your permission.

L. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions about the study, please contact the research Investigator or study staff as listed below:

Massachusetts General Hospital:

- Alphonse Taghian, MD, PhD: (617) 726-5060
- Melissa Skolny, MSHA: (617) 643- 2808
- Cynthia Miller, BS: (617) 643- 1306

DFCI Protocol Number:	11-325	Approved Date (DFCI IRB Approval):	03/04/2019
Date Posted for Use:	03/04/2019	Expiration Date (Invalid for use on or after):	03/04/2020
Version Date (OnCore):	03/04/2019	Content Last Revised with OHRS Review:	AM #12

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at DFCI (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

M. PRIVACY OF PROTECTED HEALTH INFORMATION

Federal law requires Dana Farber/Harvard Cancer Center (DF/HCC) and its affiliated research Investigators, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions ("protected health information"). If you enroll in this research study, your "protected health information" will be used and shared with others as explained below.

1. **What protected health information about me will be used or shared with others during this research?**

   - Existing medical records
   - New health information created from study-related tests, procedures, visits, and/or questionnaires

2. **Why will protected information about me be used or shared with others?**

   The main reasons include the following:
   - To conduct and oversee the research described earlier in this form;
   - To ensure the research meets legal, institutional, and accreditation requirements;
   - To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); and
   - Other reasons may include for intervention, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care.

DFCI Protocol Number:	11-325	Approved Date (DFCI IRB Approval):	03/04/2019
Date Posted for Use:	03/04/2019	Expiration Date (Invalid for use on or after):	03/04/2020
Version Date (OnCore):	03/04/2019	Content Last Revised with OHRS Review:	AM #12

3. Who will use or share protected health information about me?

- DF/HCC and its affiliated research Investigators and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

4. With whom outside of DF/HCC may my protected health information be shared?

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

- Outside individuals or entities that have a need to access this information to perform functions on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- The sponsor(s) of the study, and its subcontractors
- Other research Investigators and medical centers participating in this research, if applicable
- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes.
- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research, if applicable

Some who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

5. For how long will protected health information about me be used or shared with others?

- There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

DFCI Protocol Number:	11-325	Approved Date (DFCI IRB Approval):	03/04/2019
Date Posted for Use:	03/04/2019	Expiration Date (Invalid for use on or after):	03/04/2020
Version Date (OnCore):	03/04/2019	Content Last Revised with OHRS Review:	AM #12

6. Statement of privacy rights:

- You have the right to withdraw your permission for the research Investigators and participating DF/HCC entities to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: Whom do I contact if I have questions about the research study?"
- You have the right to request access to your protected health information that is used or shared during this research and that is related to your intervention or payment for your intervention, but you may access this information only after the study is completed. To request this information, please contact the researcher listed above in the section: "Whom do I contact if I have questions about the research study?"

DFCI Protocol Number:	11-325	Approved Date (DFCI IRB Approval):	03/04/2019
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Version Date (OnCore):	03/04/2019	Content Last Revised with OHRS Review:	AM #12

O. DOCUMENTATION OF ASSENT

Signature of participant under age 18: The person doing this research study has explained what will happen to me if I take part in this research study. My signature below means that I want to be in this research study. I can decide not to take part in this research study if I don't want to and nothing at all will happen if I decide I do not want to participate.

_____ _____
Signature of Participant Date

To be completed by person obtaining assent:

The assent discussion was initiated on_____(date).

☐ The information was presented in age-appropriate terms. The minor:
- ☐ Agreed to take part in the study
- ☐ Did not agree to take part in the study

☐ An assent discussion was not initiated with the minor for the following reason(s):
- ☐ Minor is incapacitated
- ☐ Minor is under 10 years of age
- ☐ Other_____

_____

Signature of Individual obtaining assent: _____

Printed name of above: _____

Date: _____

DFCI Protocol Number:	11-325	Approved Date (DFCI IRB Approval):	03/04/2019
Date Posted for Use:	03/04/2019	Expiration Date (Invalid for use on or after):	03/04/2020
Version Date (OnCore):	03/04/2019	Content Last Revised with OHRS Review:	AM #12

P. DOCUMENTATION OF CONSENT

My signature below indicates my willingness to participate in this research study and my understanding that I can withdraw at any time.

Signature of Participant or Legal Guardian

Date

DFCI Protocol Number:	11-325	Approved Date (DFCI IRB Approval):	03/04/2019
Date Posted for Use:	03/04/2019	Expiration Date (Invalid for use on or after):	03/04/2020
Version Date (OnCore):	03/04/2019	Content Last Revised with OHRS Review:	AM #12

To be completed by person obtaining consent:

The consent discussion was initiated on_____(date).

☐ A copy of this signed consent form was given to the participant or legally authorized representative, or, where the participant is a minor, the participant's parent or legal guardian.

For Adult Participants

☐ The participant is an adult and provided consent to participate.

☐ Participant is a non-English speaker and signed the translated Short Form in lieu of English consent document

As someone who understands both English and the language spoken by the participant, I interpreted, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____

☐ The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:

☐ gave permission for the adult participant to participate

☐ did not give permission for the adult participant to participate

or

For Minor Participants

☐ The parent or legally authorized representative gave permission for the minor to participate.

☐ Participant is a non-English speaker and signed the translated Short Form in lieu of English consent document

As someone who understands both English and the language spoken by the participant, I interpreted, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.

DFCI Protocol Number:	11-325	Approved Date (DFCI IRB Approval):	03/04/2019
Date Posted for Use:	03/04/2019	Expiration Date (Invalid for use on or after):	03/04/2020
Version Date (OnCore):	03/04/2019	Content Last Revised with OHRS Review:	AM #12

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____

☐ The parent or legally authorized representative did not give permission for the minor to participate

Signature of Individual obtaining consent: _____

Printed name of above: _____

Date: _____

DFCI Protocol Number:	11-325	Approved Date (DFCI IRB Approval):	03/04/2019
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Version Date (OnCore):	03/04/2019	Content Last Revised with OHRS Review:	AM #12