Protocol Title: Prospective screening for lymphedema: Analysis of objective measurements, symptoms, functionality, and quality of life questionnaires to evaluate lymphedema in patients following treatment for breast cancer.
Partners Protocol#: 2008-P-000540. NCT01521741.
Principal/Overall Investigator: Alphonse Taghian, MD, PhD
Descriptions of Study Population: Women being treated for breast cancer.

This fact sheet tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. If you have any questions about the research or about this form, please ask us. Please understand that y**our participation in this study is your choice. You may decide not to participate at any time, and it will not affect your medical care.**

Why is this research being done? The purpose of this research study is to evaluate any changes you may experience in your arms during and after treatment for breast cancer by collecting information about your symptoms and performing measurements on your arms. We are asking you to take part in this study because you are being treated for breast cancer and are at risk for lymphedema (swelling of your arm after lymph node removal or radiation to the lymph nodes). About 10,000 people will take part in this research study.

How long will I take part in this research study?
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 and questionnaires, which will take no more than 7-12 minutes to complete at each visit. The questionnaire may be completed electronically on a tablet in clinic, sent via unencrypted email, or on paper. If you consent to receive unencrypted email, this means that no additional sign-on is required to view the content of the email and you will be asked to provide an email to be used for the purposes of this study only where you feel comfortable receiving unsecure email. The email you receive will not contain any of your personal information or any information about this study.
The Mass General Brigham standard is to send emails securely. Due to our survey methods, we cannot send emails securely, but we can provide alternate methods of completing the survey. These "unencrypted" emails will not be secure and could result in the unauthorized use or disclosure of your information. If you agree to receive communications by unencrypted email despite the risks, Mass General Brigham will not be held responsible. Your preference to receive unencrypted email will apply to emails sent to you from the research staff in this study. If you wish to communicate with other research staff at Mass General Brigham regarding additional studies, your preference will have to be documented within each research group.

What will happen in this research study?
During the study, whenever you have an arm measurement you will be asked to complete a questionnaire. While completing the questionnaire, you may skip any questions you do not wish to answer. You will not be asked to make any extra appointments as part of this study; however, you may request arm measurements when you are at the hospital at any time. Measurements will be taken every 2-12 months. Measurements will be taken with two devices: the SOZO and the Perometer. Neither device causes a risk to you. The Perometer measures arm volumes using infrared light. You put your arm through a frame that slides back and forth. The SOZO machine measures the amount of fluid in your at-risk arm by using electrical currents that cannot be felt. You stand on the machine with bare feet and hold two handlebars. Both measurements only take a few seconds. These measurements will be taken when you are at MGH for your regular medical visits.
Your medical chart will be reviewed to collect information about your breast cancer treatment. This information will be stored in a secure and password protected database. Only MGH research staff will have access to this information.. This information will help us determine any risk factors associated with lymphedema. We will use this database to answer research questions we have about lymphedema, such as how specific breast cancer treatments affect lymphedema risk. ImpediMed, the manufacturer of the SOZO device, has limited access to data collected by the device. Proper agreements have been made to protect your data.

What are the risks and possible discomforts from being in this research study?
The only foreseeable risks or discomforts from being in this research study would be due to feelings of concern related to possible symptoms of lymphedema or changes in your arms.

What are the possible benefits from being in this research study?
This research will allow you to evaluate any changes in your arms during treatment and advance the field of breast cancer-related lymphedema research.

Can I still get medical care within Partners if I don't take part in this research study or if I stop taking part?
Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty and you won't lose any benefits you receive now or have a right to receive in the future. Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

If you take part in this research study, and want to drop out, you should tell us.

If I have questions or concerns about this research study, who can I call?
You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want. Cheryl Brunelle is the contact person for this research study who can answer questions you may have. You can call her at 617-724-0127, Mon.-Fri. 9am-4:30pm. If you would like to schedule additional measurements for any reason, please call our clinic at 617-643-1306.
If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.
You can talk to them about: your rights as a research subject, your concerns about the research, a complaint about the research. Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

We are required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of health information obtained for research. This is an abbreviated notice, and does not describe all details of this requirement. During this study, identifiable information about you or your health will be collected and shared with the researchers conducting the research. In general, under federal law, identifiable health information is private. However, there are exceptions to this rule. In some cases, others may see your identifiable health information for purposes of research oversight, quality control, public health and safety, or law enforcement. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy.