Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: **Improving diagnostic US for reduction of benign breast biopsies using US-guided Optical Tomography**

Principal Investigator: **Debbie Bennett, MD**

Research Team Contact: **Megan Luther (314) 747-2012**

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are scheduled for an Ultrasound guided biopsy or fine needle aspiration of a breast abnormality that can be seen with Ultrasound.

The main purpose of this research is to see if adding optical imaging with near infrared light to breast Ultrasound can improve the accuracy of the Ultrasound exam and lower the rate of unnecessary biopsy.

For patients who have had a contrast enhanced mammogram (CEM), a secondary purpose of this research is to compare the results of optical imaging with the CEM exam.

The research uses a combination of Near Infrared light and Ultrasound (NIR/US) in a technique called Ultrasound guided diffuse optical tomography (DOT).

The NIR/US imaging device is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration (FDA).

WHAT WILL HAPPEN DURING THIS STUDY?

In order to ensure that you are eligible to participate in this study, we will have to confirm your diagnosis and treatment plan. If you are eligible to continue in the study and choose to continue, you will be scheduled for NIR/US imaging as an outpatient in the Department of Radiology before your clinically scheduled ultrasound-guided biopsy.

The NIR/US device is a handheld device that involves using red light delivered by laser diode (similar to a checkout scanner at the supermarket). You will be scanned lying down which is the position you were in when you received your standard ultrasound. The handheld probe will touch your skin. The standard disinfecting wipes used for cleaning ultrasound transducers will be used to clean the handheld probe before and after each patient. It takes about 10 minutes to complete each scan. The results of these scans will not be used to make any changes to your standard of care procedure.

Up to 20 patients who enroll in this research study may also have a contrast enhanced mammogram (CEM). If this does not occur as part of your standard of care, you may be asked to have this exam as part of this study. The CEM is a mammogram of both breasts after the intravenous (IV) injection of iodinated contrast material.

We will also collect data from your medical record, including demographics (such as your age), medical record number (MRN), imaging reports (such as mammograms, ultrasounds, PET, MRIs, etc.), biopsy, surgery and pathology reports if available.

Will you save my samples or research data to use in future research studies?

As part of this study, we are obtaining data from you. We would like to use this data for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding cancer, or other diseases or conditions, including research to develop investigational tests, treatments, or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data you give up any property rights you may have in it.

We will share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your data for future research you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 335 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for up to 6 months, although your active participation will only involve one extra NIR/US scan (approximately 10 minutes long) as described above.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Risks of NIR/US Scans
There are no known risks or discomforts associated with the experimental NIR/US scans. The light used during the NIR/US may cause injury to your eyes. To prevent eye injury, the research team will not turn on the source light until the NIR/US probe is in contact with your skin. Use of ultrasound may heat your breast tissue and could, in extreme situations, result in localized heating and be uncomfortable.

Risk of CEM Exam
Risks Associated with Radiation Exposure
Contrast-enhanced mammography is performed with x-ray radiation similar to a regular mammogram. The amount of radiation averaged over your entire body, is approximately 53% of the amount of radiation exposure all people in St. Louis receive each year from naturally occurring radiation sources. The risk from the radiation exposure in this study is too small to be measured. It is not a big risk when compared with other risks you take every day. Please see the "Radiation Fact Sheet" located at http://hrpo.wustl.edu or ask the study staff for a copy.

Risks Associated with Iodinated Contrast
Severe: Severe allergic reactions may be life threatening but are very rare (approximately 1/ 2,500). IV contrast rarely causes kidney injury that can lead to kidney failure. It can also rarely cause shock and cardiac arrest.

Moderate: Moderate allergic reactions are not life threatening but require treatment, such as abnormal (too fast or too slow) heart rate high or low blood pressure, shortness of breath, rash or hives, swelling of the throat or fluid on the lungs).

Mild: Mild reactions include nausea, vomiting, mild abdominal discomfort, itching, cough, headache, sweating, rash, anxiety, chills and/or flushing.

Risks Associated with Intravenous (IV) Catheter
The placement of an IV (small plastic catheter tube) in your arm may be associated with mild discomfort and bleeding. Bruising, clotting, leakage of contrast into the tissues causing pain or tissue necrosis are less likely. Infection at the site can occur but is rare.

Breach of Confidentiality
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study and the NIR/US technology will lower the rate of unnecessary breast biopsy.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. You should receive the check about three weeks after you complete your participation in this study. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

You will be paid $50 total for this one NIR/US scan that you have.

WHO IS FUNDING THIS STUDY?

National Institutes of Health (NIH) is funding this research study. This means that Washington University is receiving payments from NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH or conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at (314) 454-7696 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- National Institutes of Health (NIH)
- Hospital or University representatives, to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and be available to your health care providers who are not part of the research team.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

The Siteman Cancer Center at Washington University School of Medicine and Barnes-Jewish Hospital is supported by funding from the National Cancer Institute (NCI). To meet NCI requirements, your protected health information relating to your participation in this study (including your social security number) will be stored in a secure database at the Siteman Cancer Center. This database and also your health care records may be reviewed by Siteman Cancer Center personnel. All information will be securely and confidentially maintained.

To help protect your confidentiality, we will store your paper records in a locked office which is in a locked suite, and your electronic data will be stored in a secure server where only members of the research team will have access. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

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.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
      - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

Can someone else end my participation in this study?

Under certain circumstances, the investigator or the NIH might decide to end your participation in this research study earlier than planned. This might happen for no reason or because

- The researcher believes that it is not in your best interest to stay in the study
- You become ineligible to participate
- You do not follow instructions from the researchers
- The study is suspended or canceled

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Bennett at (314) 454-7696 or Megan Luther at (314) 747-2012. If you experience a research-related injury, please contact: Dr. Bennett at (314) 454-7696 or Megan Luther at (314) 747-2012.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 11/12/25.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

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(Name of Person who Obtained Consent - printed)