**Participant Information and Consent Form**

**Ultrasound acoustic shadow detection:**

**laboratory study of ultrasound imaging algorithms**

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1. **Invitation**

You are being invited to take part in this research study to assist the development of new ultrasound imaging segmentation methods. The goal is to develop an automated way to detect regions in 2D ultrasound images known as acoustic shadows. This is useful for doctors to identify regions of the ultrasound image that may be affected by materials that reflect an ultrasound signal and obscure the visualization of tissue. The identification of acoustic shadows is useful for training new ultrasound operators in recognizing what is displayed in an ultrasound image and for large scale algorithms that region shadow regions on many ultrasound images to be identified in an efficient manner. One example of using these methods is to identify the presence of an air-gap between the ultrasound transducer and skin by observing an acoustic shadow spanning the entire length of an ultrasound image.

1. **Your participation is voluntary**

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other servicesto which you are entitled or are presently receiving.

You should be aware that the research study may include procedures that are not part of standard practice or are not yet proven. This consent form describes the imaging procedures that are being carried out for research purposes. Please review the consent document carefully when deciding whether or not you wish to be part of the research and sign this consent only if you accept being a research participant.

If you wish to participate in this study, you will be asked to sign this form.

Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

1. **Who is conducting this study?**

This study is being conducted by Prof. Robert Rohling at the University of British Columbia. It is sponsored by the Canadian Institutes for Health Research, in collaboration with the Natural Sciences and Engineering Research Council.

1. **Background**

Ultrasound is a popular imaging technology that is widely used in clinics and hospital as it does not produce ionizing radiation and is relatively less expensive compared to computed tomography (CT) or magnetic resonance imaging (MRI) scanning. Thus, there is a strong motivation to use ultrasound more widely and recently ultrasound technology has developed ultrasound devices that are much smaller and cheaper. A difficulty in ultrasound is the presence of artifacts in an ultrasound image which obscure the image and make the interpretation of ultrasound images difficult. One artifact is acoustic shadowing, where aan ultrasound signal reaches a boundary between two materials that are significantly different in acoustic impedance and the signal is almost completely reflected. On the image, this manifests as a dark regions down the scanline beyond the boundary. The dark region, or “shadow”, obscures the region and may be difficult to interpret.

Acoustic shadows are specifically present when there is a tissue-to-bone boundary or an air-to-tissue boundary. There is a motivation to detect both scenarios as an automated acoustic shadow detection algorithm can help train new users of ultrasound to interpret ultrasound imaging. For instance, the detection algorithm can notify the user if an acoustic shadow due to an air gap between the ultrasound probe and skin is detected and the user would recognize that better probe contact is required to generate the desired images. In addition, many large-scale image processing techniques would benefit from an automated method of detecting features, such as training a machine learning model to recognize bones. As manually highlighting acoustic shadow regions is tedious, an automated shadow detection method can provide other image processing algorithms with the shadow regions recognized. Researchers at the University of British Columbia have been developing new ultrasound imaging methods to automatically detect acoustic shadow regions. These new methods can be tested on healthy adult participants as the first step in assessing the quality of the new images.

1. **What is the purpose of the study?**

This feasibility study is done to test the new ultrasound imaging methods on healthy adults. This type of study involves a small number of participants and so it is not expected to prove safety or effectiveness. The results may be used as a guide for larger studies, although there is no guarantee that they will be conducted. Participation in a feasibility study does not mean that you will be eligible to participate in a future larger study. Knowledge gained from feasibility studies may be used to develop future studies that may benefit others.

In particular, ultrasound images of the participants will be taken and assessed with a number of measures of image quality. These measures will be used to determine whether the new imaging methods outperform existing imaging methods. Images will be taken from several different views of the anatomy and with different imaging parameters. The long-term aim is to provide healthcare providers with a new generation of ultrasound machines with improved usability.

1. **Who can participate in this study?**

You may be able to participate in this study if*:*

* You are at least 18 years of age (adult participants)

1. **Who should not participate in this study?**

You will not be eligible to participate in this study if:

* You have any known disease of your muscles or skeleton
* You have received an operation or procedure related to your muscles or skeleton
* You are suffering from pain or dysfunction related to your muscles or skeleton

1. **What does the study involve?**

If you agree to take part in this study, the procedures and visits you can expect will include the following:

* An ultrasound scan will be performed on a portion of your skeleton such as your ribcage or your forearm. This will take approximately 20 minutes. The ultrasound data is saved for later study – it will not be used here for any diagnosis or evaluation.
* To perform the ultrasound examination, the ultrasound probe must be placed against the skin surface. This means loose-fitting clothing should be worn so that a small area of the skin surface can be exposed.

The ultrasound images will be de-identified and saved on a computer using a unique numbering system that does not include any personal information; i.e. your name will not be recorded.

To assist the research, one or two persons (maximum two) will be present performing the ultrasound scan. This person(s) is one of the following: a student (doing the research on image processing), or Dr. Rohling (the technical lead investigator). The student is from the Faculty of Applied Science and has received at least five months training in the area of ultrasound imaging. They will be using these studies for their research, but, like the others, will keep participant confidentiality. Dr. Rohling may be present simply to observe. No other people will be present during the ultrasound examination.

1. **What are my responsibilities?**

None

1. **What are the possible harms and discomforts?**

Since ultrasound does not pose any known health hazards, there are no known harms or side effects from participating in this study.

1. **What are the potential benefits of participating?**

You will not benefit from this study. We hope that the information learned from this study can be used in the future to benefit other people in need of ultrasound. One of the possible future benefits for patients is the translation of the techniques developed in our lab into techniques used in a clinical environment.

1. **What are the alternatives to the study treatment?**

No treatments are involved in this study, so alternative treatments are not applicable.

1. **What if new information becomes available that may affect my decision to participate?**

Since this study involves only one ultrasound examination, there is no new information that will be relevant.

1. **What happens if I decide to withdraw my consent to participate?**

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, you have the right to request the withdrawal of your information collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please let your study investigator know.

1. **Can I be asked to leave the study?**

Since there is only one ultrasound examination for you, once this examination is completed, your participation is complete. The investigators may decide to discontinue the study at any time, which may result in a cancellation of a planned examination.

1. **How will my taking part in this study be kept confidential?**

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator and the Canadian Institutes for Health Research, and UBC Clinical Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected. You also have the legal right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

1. **What happens if something goes wrong?**

By signing this form, you do not give up any of your legal rights and you do not release the participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan.

There is a small chance that the ultrasound examination will reveal the possibility of an injury, pathology, disease or other medical condition. This is called an incidental finding and you will be notified verbally of a possible incidental finding at the time of examination. The principle investigator will prepare and deliver a short written report in collaboration with the investigator who performed the ultrasound scan with the recommendation that you discuss the incidental finding with your general practitioner.

1. **What will the study cost me?**

All research-related medical care and treatment and any related tests that you will receive during your participation in this study will be provided at no cost to you.

You will also not be paid for participating in this study.

1. **Who do I contact if I have questions about the study during my participation?**

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contacteither Professor Rohling at (604)822-2045.

1. **Who do I contact if I have any questions or concerns about my rights as a participant?**

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at [RSIL@ors.ubc.ca](mailto:RSIL@ors.ubc.ca) or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

1. **After the study is finished**

You may wish to read the publications of this research, which will be posted on the Principal Investigator’s website: www.ece.ubc.ca/~rohling

**Signatures**

**Ultrasound acoustic shadow detection: laboratory study of ultrasound**

**imaging algorithms**

**Participant Consent**

My signature on this consent form means:

* I have read and understood the information in this consent form.
* I have had enough time to think about the information provided.
* I have been able to ask for advice if needed.
* I have been able to ask questions and have had satisfactory responses to my questions.
* I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
* I understand that my participation in this study is voluntary.
* I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
* I understand that I am not waiving any of my legal rights as a result of signing this consent form.
* I understand that this study will not provide any benefits to me.

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Participant’s Signature Printed name Date

Signature of Person Printed name Study Role Date

Obtaining Consent

If this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, indicate:

Language: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Was the participant assisted during the consent process in one of ways listed below?

⬜ Yes ⬜ No [Note: For typical situations where the person conducting the consent discussion simply reads the consent with the participant to ensure that informed consent is properly obtained, check “no”.]

If yes, please check the relevant box and complete the signature space below:

⬜ The consent form was read to the participant, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant (please check if participant is unable to read ).

⬜ The person signing below acted as an interpreter/translator for the participant, during the consent process (please check if an interpreter/translator assisted during the consent process).

Signature of Person Assisting Printed Name Date

in the Consent Discussion

Investigator Signature Printed name Date

My signature above signifies that the study has been reviewed with the study participant by me and/or by my delegated staff. My signature may have been added at a later date, as I may not have been present at the time the participant’s signature was obtained.