**JOHNS HOPKINS UNIVERSITY**

**HOMEWOOD INSTITUTIONAL REVIEW BOARD (HIRB)**

**RESEARCH PARTICIPANT INFORMED CONSENT FORM**

**Study Title**: Ultrasound scanning though cooperatively controlled robot arm for reducing sonographer strain

Application No.: HIRB00008883

**Principal Investigator**: Emad Boctor

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You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

1. **Research Summary (Key Information):**

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

This work is a continuation and improvement of previous ultrasound robotic assist prototypes aimed to help relieve sonographers of their physical exertion during scanning, while helping them to acquire good images. The purpose of this research study is to determine the effectiveness of our new system versus previous prototypes, as well as non-robotic freehand ultrasound scanning. Participants will be asked to perform several trials of ultrasound tasks by manipulating an ultrasound probe by hand, both with and without the robotic assist. Optionally, the participant will be asked to wear adhesive surface EMG (sEMG) pads while performing these trials, which help to quantify muscle exertion by measuring the voltages in muscle. Total participation time for a participant would be one session of approximately one hour duration.

The greatest risks of this study include unintended/unexpected movement of the robot while operating it. Additionally, if a participant chooses to enroll in the optional study, there is a slight risk of skin irritation upon removal of the adhesive sEMG pads similar to what one might get when removing a bandaid.

1. **Why is this research being done?**

This research is being done to investigate the effectiveness of a new robot assistance algorithm in reducing sonographer strain during ultrasound procedures. The goals of this system are to assist the sonographer in acquiring high-quality images, while minimizing the chance of work-related injuries due to the physical exertion often required when taking an ultrasound scan.

People with experience in robotics or using ultrasound probes (either in a lab or clinical setting) may join.

We anticipate that about 30 people will take part in this study, which is solely taking place on the JHU Homewood campus.

1. **What will happen if you join this study?**

If you agree to be in this study, we will ask you to perform the below two tasks with four different scanning scenarios, conducting five trials for each scenario. This equals 2×4×5=40 trials overall, which should take approximately 1 hour total to complete and will be performed at our testing site in Hackerman Hall on the Homewood campus. The order in which the tasks and scanning scenarios are performed will be randomized by drawing a number out of a hat.

Tasks:

1. Maneuver the robotic system to apply a 20N (approx. 2kg = 4.4lbs) contact force for 20 seconds on a phantom (a plastic slab that mimics the rigidity of human tissue) with and without robot assistance
2. Maneuver the robotic system to apply a 20N contact force while following an internal feature embedded within the phantom (similar to if a sonographer were tracing a vein during a scan) with and without robot assistance.

Scanning scenarios:

1. Freehand scanning
2. Freehand scanning with visual force feedback
3. Scanning with robotic system without force constraint
4. Scanning with the robotic system with maximum force constraint.

After performing the two tasks for five trials of each scanning scenario, two brief questionnaires will be issued to learn about your previous ultrasound experience, as well as ask you questions relating to your evaluation of the robotic ultrasound assist system you operated today. Typically these questions ask you to rate some aspect of your experience “on a scale from 1 to 5.”

**Optional Component:**

You may still take part in the main study even if you say “no” to this optional component. You may also choose to stop participating in this optional component at any time and still continue to take part in the main study.

The study team is interested in the effects that robotic ultrasound assistance has on exerted muscle force, a metric measured by surface EMG (sEMG) sensors which have the ability to read muscle voltages. These sensors are simple adhesive electrode pads that, for our purposes, will be placed on a participants forearm and scanning shoulder. The electrodes purely measure muscle exertion and do not output any signals into your body. The placement of these pads can either be performed by the participant, or with assistance from a researcher or person of the participant’s choosing. Essentially, this optional component would ask you to wear two of these sensors while performing the main study tasks listed above. Please indicate if you would like to take part in this optional component below:

**Yes € \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Participant Date

**No €** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant Date

**How long will you be in the study?**

You will be in this study for approximately one hour.

1. **What are the risks or discomforts of the study?**

While all efforts will be made to secure your data and store it in a confidential way, participation does involve slight risk for the loss of confidentiality of information including your survey responses and, if you take part in the optional study, sEMG readings.

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

The risks associated with participation in this study are no greater than those encountered in daily life or during the performance of routine physical examinations. Although it is very unlikely, during maneuvering, the robot might not respond to your commands as expected, in which case you should let go of the ultrasound probe and tell the inspector about your discomfort and experience.

There is additionally a minimal possibility, if you take part in the optional study, that the sEMG electrodes used to measure muscle exertion cause minimal skin irritation upon removal due to their adhesive, which would be no more severe than that experienced when removing a bandaid.

1. **Are there benefits to being in the study?**

There is no direct benefit to you from being in this study.

This study may benefit sonographers if the results lead to a better understanding of how robotic assistance affects the amount of force they must exert during an ultrasound scanning procedure, while also aiding them in acquiring better images.

1. **What are your options if you do not want to be in the study?**

Your participation in this study is entirely voluntary. You choose whether to participate.

If you decide not to participate, there are no penalties, and you will not lose any benefits to which you would otherwise be entitled.

If you do not join, your employment/education at Johns Hopkins will not be affected.

1. **Will it cost you anything to be in this study?**

No.

1. **Will you be paid if you join this study?**

No.

1. **Can you leave the study early?**
* You can agree to be in the study now and change your mind later, without any penalty or loss of benefits.
* If you wish to stop, please tell us right away.
* If you want to withdraw from the study while participating, please let the experiment investigator know and let go of the ultrasound probe.
* If you want to withdraw from the study after participating, please contact the experiment inspector or the PI.
* Leaving this study early will not affect your employment/education.
1. **Why might we take you out of the study early?**

You may be taken out of the study if:

* Staying in the study would be harmful.
* You fail to maneuver the robot safely during a short training session before the study.

If you are taken out of the study early, Johns Hopkins may use or give out your information that it has already collected if the information is needed for this study or any follow-up activities*.*

1. **How will the confidentiality of your data be protected?**

Any study records that identify you will be kept confidential to the extent possible by law. The records from your participation may be reviewed by people responsible for making sure that research is done properly, including members of the Johns Hopkins University Homewood Institutional Review Board and officials from government agencies such as the National Institutes of Health and the Office for Human Research Protections. (All of these people are required to keep your identity confidential.) Otherwise, records that identify you will be available only to people working on the study, unless you give permission for other people to see the records.

Study records will be marked by a given, unique participant number. The key linking names with participant numbers will be destroyed once all data for this study has been collected. All records will be securely kept in a locked file cabinet (which only the researchers will have access to) until transferred to a secure Whiting School of Engineering database.

1. **What other things should you know about this research study?**

**What is the Institutional Review Board (IRB) and how does it protect you?**

This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study.  You may contact the IRB at 410-516-6580 or hirb@jhu.edu.

**What should you do if you have questions about the study?**

Call the principal investigator, Dr. Emad Boctor at 443-845-6592. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-516-5680.

You can ask questions about this research study now or at any time during the study, by talking to the researcher(s) working with you or by calling Kevin Gilboy, the primary graduate student researcher conducting the study, at 732-567-1815.

If you have questions about your rights as a research participant or feel that you have not been treated fairly, please call the Homewood Institutional Review Board at Johns Hopkins University at (410) 516-6580.

1. **What does your signature on this consent form mean?**

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form, and you agree to join the study. You will not give up any legal rights by signing this consent form.

**WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM**

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Signature of Participant (Print Name) Date/Time

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Signature of Person Obtaining Consent (Print Name) Date/Time

**NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT.**