UNIVERSITY OF WATERLOO

STANDARD OPERATING PROCEDURE

Protocol for Completing an Ultrasound from Research Study Participants

SOP ContAct-003

SOP created: November 17, 2016
Approved by: Clinical Research Ethics Committee
Approved: May 11, 2017

A. PURPOSE AND BACKGROUND

Applying or ordering the application of a form of energy is considered a controlled act. This SOP describes the procedures for researchers to conduct a study with participants using an ultrasound device.

B. DATA/IMAGES COLLECTED

1. Types of images collected in accordance with this SOP:
    a. Images and videos of ultrasound scans
    b. Doppler velocity signals

2. Types of images NOT collected in accordance with this SOP:
    a. Invasive scans such as transrectal, transesophageal, and transvaginal
    b. Obstetric or fetal scans
    c. Ophthalmic or eye scans
    d. Gas contrast/microbubbles

Any data/images to be collected for the above (2a – 2d) will require a separate SOP.

C. PROCEDURES/STUDY PROTOCOL

1. The participant is invited to take a comfortable seat or lie down on the bed, depending on the study protocol.

2. The researcher applies ultrasound gel to a probe, makes contact between the probe and the skin, and optimizes the image or signal by adjusting the settings on the device and/or adjusting the position of the probe.

3. Baseline or **resting** images/signals are recorded, often followed by an **intervention** or activity and then **follow-up** images are collected. The nature of the intervention will vary, depending on the research study hypotheses. Examples of interventions (requiring separate research ethics approval) might include activities such as completing a bout of exercise, having electrodes inserted, consuming a meal, or taking a medication. The entire sequence (resting, intervention, follow-up) may be repeated several times, again depending on the type of study.

4. When the ultrasound measurement(s) is/are completed, the researcher lifts the probe off the skin and wipes the gel off the skin and/or hair with a disposable cleaning tissue (e.g., Kimwipe).

5. Upon completion of the ultrasound measurement(s), probes are cleaned by wiping them with disinfectant towelettes (e.g., Cavi-wipes).

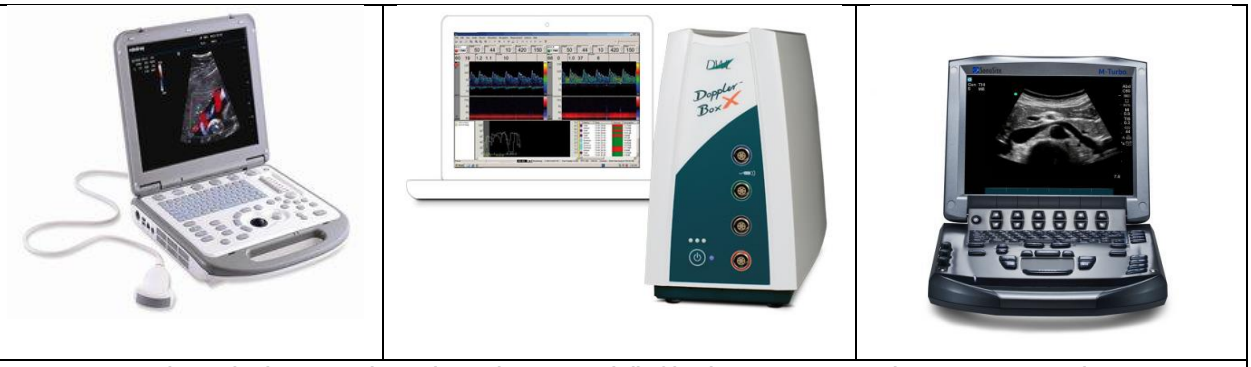
6. The participant is thanked for his/her participation.

D. EQUIPMENT

Only commercial off-the-shelf (COTS) ultrasound devices with FDA and/or CE approval will be used. Non-COTS ultrasound devices and devices that are not FDA/CE approved are not the topic of this SOP and will require separate research ethics approval (and possibly additional processes). Contact the research ethics office.

At time of writing this SOP, there is a large commercial ultrasound market which includes dozens of brands such as GE, DWL, Philips, Toshiba, Samsung, etc. To achieve FDA and/or CE safety certifications, individual companies must have demonstrated to the industry regulatory bodies that the devices they sell meet the strict safety standards set out by the FDA and/or CE.

The devices used may look similar to these below:



The Mindray M5 imaging ultrasound (left), the DWL Doppler BoxX Doppler ultrasound device (centre), and the SonoSite M-Turbo (right) are shown above.

Supplies used during ultrasound scans include (but are not limited to):

- ultrasound gel,
- disinfectant wipes,
- paper towels, and
- gloves.

*Disposable, single use materials or equipment are to be used whenever possible and any reusable materials or equipment must be cleaned and disinfected with sanitizers before being used with another participant.

E. DESCRIPTION TO STUDY PARTCIPANTS

1. In the information-consent letter participants will be informed:

    - the ultrasound will be conducted by a researcher trained and experienced in the use of ultrasound who has been delegated to conduct the procedure by a physician,
    - the clothing that is appropriate to wear for the ultrasound session, and
    - questions are welcome at any time and they may request to stop the procedure at any time.

F. RISKS

1. PARTICIPANTS

    - General anxiety
    - Irritation from the ultrasound gel
    - Skin burn if the transmission power is set too high

2. RESEARCHERS

    - There are no known risks to the researchers implementing the procedure as a result of the procedure itself, or the equipment.

G. SAFEGUARDS/SAFETY PROCEDURES

1. PARTICIPANTS

    - To minimize general anxiety, a familiarization period will be used to explain the ultrasound procedure to participants including the equipment used during the ultrasound and participants will be given time to ask questions prior to participating.

    - Universal precautions are be applied at all times. Refer to the Canadian Public Health Association universal precautions guidelines: http://www.cpha.ca/uploads/portals/idp/19661e.pdf.

    - The researcher will follow the ALARA (As Low As Reasonably Achievable) Principle for ultrasound power output. See http://hc-sc.gc.ca/ewh-semt/pubs/radiation/01hecs-secs255/index-eng.php.

    - Participants will be asked to indicate to the researcher if the ultrasound probe feels too warm.

    - Irritation from the ultrasound gel can occur. Participants will be asked prior to participating whether they have are sensitive or have had an allergic reaction to ultrasound gel. If they indicate they are sensitive/have an allergy, participants will be told they are ineligible to participate in the study.

    - If a skin burn should occur, the researcher will treat the burn by applying a cold compress and a sterile covering.

2. RESEARCHERS

- The researcher is to have completed:
    - First Aid/CPR training
    - University of Waterloo workplace safety training through the Safety Office with particular attention paid to those modules relevant to safely conducting research in human research laboratories.

- Under conditions where the researcher might be exposed to blood or bodily fluids, a new pair of disposable nitrile/vinyl gloves will be used with each participant. Gloves are to be for single-procedure use only. Gloves should always be removed using a glove-to-glove or skin-to-skin technique to prevent contaminating the hands. Gloves are to be disposed in an appropriate container.

- The use of gloves does not replace the need for hand hygiene. Hands should be properly washed before the gloves are put on and after the gloves are removed. Hand hygiene is also needed before and after the replacement of gloves during a procedure or in between tasks.

H. REFERENCES

Public Health Ontario (2013). *Best Practices for Cleaning Disinfection and Sterilization of Medical Equipment/Devices in all Health Care Settings, 3rd edition*. Retrieved on July 16, 2015 http://www.publichealthontario.ca/en/eRepository/PIDAC_Cleaning_Disinfection_and_Sterilization_2013.pdf

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