Harvard University

# **Detailed Guidance for Human Subject Research: Ultrasound Imaging**

This is specific guidance for preparing, operating, and cleaning electromyography (EMG) devices. In addition to the device specific procedures illustrated below, general human subject research guidance and research lab specific guidance will be followed during all research activities.

**Pre-Visit Screening Procedures**

* Call the participant and complete the Coronavirus Pre-Visit Screening Form using the participant script prior to visit.
* All study team members complete Coronavirus Screening Form.

**General Procedures**

* All study team members and the participant wash their hands upon arrival and after any physical contacts with other people.
* All study team members and the participant wear university-supplied surgical-grade facemasks at all times. Anyone who wants to take off the mask (for taking breaks or drinking water) does so at least 6 ft away from others and in advance notifies all the others present in the testing location to ensure adequate distancing during the break.
  1. Additional PPE such as face shields, goggles, sterile gloves, and gowns may be used for the participant and/or the study team members in any part of the study visit.
  2. After every use of reusable PPE (e.g. face shields), they are cleaned and sanitized using Lysol Disinfecting Wipes/Spray or equivalent.
     1. Note: See [EPA (US Environmental Protection Agency) website](https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2) for the full list of disinfectants for use against SARS-CoV-2.
* During the study visit, up to two study team members can be present at the testing location, but no close contact occurs between them (i.e. the two persons cannot work on the same task together) and they should maintain a 6 ft distance at all times.
* During the study visit, only one designated study team member can make close contact (less than 6 ft apart) with the participant for all procedures that require close contact. Close contact should be minimized, and only occurs as outlined in **red** below and when otherwise required to ensure the participant’s safety.
  1. During close contact, the designated study team member wears a face shield, and if possible, the designated study team member and the participant face opposite directions.
  2. When additional PPE (e.g. face shields) are used during close contact, the designated study team member (i) first puts on his/her own PPE while maintaining 6 ft distancing, (ii) approaches to the participant and dons PPE for the participant, (iii) carries out the close contact tasks, (iv) doffs the PPE from the participant, and (v) takes 6 ft distancing from the participant and then takes off his/her own PPE.
* The participant’s personal belongings are placed in a designated storage space, and the study team members should not touch them.
  1. The participant may be asked to bring their own bottle of water. It will be placed near the testing site where the participant can access during breaks, and same with the other belongings, the study team members should not touch the water bottle.
* All materials are handled on a clean/sanitized surface, e.g. desks or benches. Anything below the waist level is considered as unclean surfaces.
* After every study visit, all non-disposable items used in the testing should be cleaned/sanitized and stored in sealable containers. Each container will have a label and a log to track when and who cleaned the contents, and the containers shouldn’t be re-open until the next use; otherwise, the contents should be cleaned/sanitized again.

**Procedures for Ultrasound Imaging**

* Preparation
  1. One person sanitizes and sets up the ultrasound imaging system and prepares adhesive tapes in advance.
* Operation
  1. Before the data collection, the designated study team member makes close contact with the participant for up to 15 minutes to place the ultrasound probe on the participant’s body. This may involve touching the participant’s skin, applying ultrasound gel (which is squeezed from the manufacturer’s bottle and is thus uncontaminated), gently moving the probe back and forth across the participant’s skin, and having brief conversations to facilitate the palpation.
     1. If appropriate for study design, participants may attach the probe on themselves to minimize close contact.
  2. During the data collection, the designated study team member may make additional close contact with the participant for up to 5 minutes to relocate or replace the probe and continue to gently move the probe back and forth across the participant’s skin.
  3. After the data collection, the participant detaches the probe and wipes off ultrasound gel on their skin by themselves using a paper towel to minimize close contact.
* Cleaning
  1. When cleaning, study team members wear disposable gowns and sterile gloves per CDC recommendation.
  2. One person cleans and sanitizes the probe and the wire using Lysol Disinfecting Wipes/Spray or equivalent.
  3. After cleaning, store the probe and the wire in a sealable container and add time and date to the cleaning log.

**Additional considerations depending on the type of experiments**

* Indoor treadmill testing
  + Treadmills that can be remotely controlled by study team members should be used.
  + The lab space will be divided into the participant's space (including the treadmill) and the study team members’ space, with any necessary close contact only occurring at the boundary. At least 6 ft must separate the treadmill and the study team members’ space, and these spaces will be marked on the floor. In case that 6 ft distance is not achievable, a plexiglass shield should be installed between the participant and study team members to achieve adequate isolation. During the data collection, no study team member enters the participant’s space unless otherwise required to ensure the participant’s safety.
  + For Bertec instrumented treadmills, the designated study team member may enter the 6-ft boundary for up to 3 minutes to lock/unlock the treadmill before/after adjusting the slope of the treadmill.
  + In case of using a safety harness, the designated study team member may make additional close contact with the participant for up to 5 minutes to don and doff the harness and connect it to the overhead hanger.
  + In case of using a heart rate monitor, the designated study team member may make additional close contact with the participant for up to 5 minutes to don and doff the heart rate monitor.