Harvard University

# **Detailed Guidance for Human Subject Research: Electroencephalography (EEG)**

This is specific guidance for preparing, operating, and cleaning electroencephalography(EEG) 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 in addition to a surgical mask, and whenever possible, the designated study team member and the participant face opposite directions. It may be helpful to use a chin rest to keep the participant’s head facing forward (but then this must be disinfected).
  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 EEG**

* Preparation
  1. In an effort to reduce the amount of time the participant is present, try to obtain a head measurement from participants in advance so the correct cap can be prepared in advance. If the cap size is not known in advance, and enough electrode sets are available, multiple caps can be prepared in the most common sizes.
  2. One person sanitizes the EEG system. This includes using Lysol Disinfecting wipes/spray or equivalent as approved by the equipment manufacturer on all parts of the EEG system, the chair participants will use, any relevant computers, and any ancillary sensors/electrodes. Particular emphasis will be placed on equipment which comes in direct contact with the subject. Whenever possible, single use items should be used (e.g. disposable electrodes instead of reusable electrodes). These items should be properly disposed of in waste repository
  3. Prepare as much of the equipment prior to the subject’s arrival as you can. This includes a gel-filled syringe, syringe tips, towels, electrode collars, gloves, and alcohol wipes, along with powering up computers and software.
  4. If you ordinarily have participants vigorously comb/brush their hair/scalp to reduce impedance, this step should be performed by the participant at home rather than in the lab.
* Operation
  1. To increase ventilation, the door to the EEG room should remain OPEN if possible. A fan will be placed in the EEG room to circulate air out into the hallway. Privacy/confidentiality will be maintained by the presence of a room divider.
  2. Talking should be minimized, focusing on the necessary instructions and answering questions about the procedure.
  3. Before the data collection, the designated study team member makes close contact with the participant for up to 30 minutes in total to fit the EEG cap and electrodes. As per Phase I Human Subject Research Guidelines by Harvard, continuous close contact will be strictly limited to 15 minutes. This may involve touching the participant’s skin, hair, and face.
     1. The following may be appropriate to reduce the duration of the electrode application procedure in some experiments:
        1. Reducing the number of electrodes
        2. Reducing or eliminating electrodes on the face (e.g., VEOG electrodes)
        3. Increasing impedance thresholds
  4. During the data collection, the designated study team member may make additional close contact with the participant for up to 10 minutes to relocate or replace the electrodes.
  5. At the conclusion of data collection, the designated study team member makes close contact with the participant for up to 5 minutes to remove the EEG cap and electrodes.
  6. Hair washing at the laboratory should be discontinued (unless the participant can do it alone in a separate room that will then be disinfected). . Instead, gel should simply be wiped from the hair to the extent possible with a tissue or gauze pad. Participants should be notified in advance that some gel will likely remain in their hair at the end of the session.
* Cleaning
  1. Investigators should wait 30 minutes after the participant leaves before re-entering the room to retrieve data (e.g. from the computers) and clean.
  2. When cleaning, study team members wear disposable gowns and sterile gloves per CDC recommendation.
  3. One person cleans and sanitizes all non-disposable materials using EPA-approved disinfectants against covid-19 (<https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>).
     1. Investigators are encouraged to contact the equipment manufacturer (e.g., Magventure, Brainsight) with questions about how different equipment is properly cleaned
  4. After cleaning, store all reusable materials in a sealable container and add time and date to the cleaning log.
  5. For any washable items (e.g., towels), the study team should bundle the laundered items in a disposable bag, and take the bag to assigned no-contact pick up point for laundry service. The study team should wear masks and gloves when picking up and replenishing clean laundry.

References:

Simmons & Luck. *Protocol for reducing COVID-19 transmission risk in EEG research.* <https://static1.squarespace.com/static/5abefa62d274cb16de90e935/t/5ed1183fc0854d3ba699c8fe/1590761536141/General+Protocol+for+EEG+during+COVID-19+05-29-2020+for+Comments.pdf>.