Harvard University

# **Detailed Guidance for Human Subject Research: Vital Signs**

This is specific guidance for taking vital signs of participants. 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. Researchers should adhere to their IRB protocol on the necessity of vital sign measurements.

**Pre-Visit Screening Procedures**

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

**General Procedures**

* Vital signs measurements necessitate close but short-term proximity between the participant and a clinical study team member.
* Clinicians are encouraged to minimize the total duration of contact with the participant as much is safely possible (use wireless monitoring whenever possible, limit frequency of vital signs measurements as deemed safe by the clinician etc.).
* 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, close contact (less than 6 ft apart) 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 different 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. Face masks will stay on at all times during this interaction.
* 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 Taking Vital Signs**

* Preparation
  1. The clinician taking vital signs prepares and sets up blood pressure cuff, stethoscope, wireless heart rate monitor etc.
* Operation
  1. Before the data collection, the designated study team member makes close contact with the participant for up to 5 minutes to take the initial vital signs and to don wireless vital sensors (i.e. wireless heart rate monitors). This may involve touching the participant’s skin.
     1. If possible, the participant doffs the wireless sensor by themselves to minimize close contact.
  2. During the data collection, when vital signs are required the designated clinician makes close contact with the participant for up to 5 minutes to take the vital signs that are not possible via wireless monitors (i.e. blood pressure).
     1. Note: Use of wireless monitors whenever possible are preferred if it minimizes the duration of total contact between the researcher and participant.
  3. After the data collection, the designated study team member makes close contact with the participant for up to 5 minutes to remove wireless sensors or, if possible, the participant doffs the wireless sensor by themselves.
* Cleaning
  1. When cleaning, study team members wear disposable gowns and sterile gloves per CDC recommendation.
  2. A study team member cleans and sanitizes the materials following detailed step-by-step procedures:

|  |
| --- |
| Using Lysol Disinfecting Wipes/Spray or equivalent,   1. Wash/sanitize hands 2. Don personal safety equipment- mask and gloves 3. For hard/wipeable items (i.e. stethoscope) use Lysol Disinfecting Wipes and wipe down all surfaces 4. For porous/non-wipeable items (i.e. heart rate band) use Lysol Disinfecting Spray    1. Lay/hang the device out on a laundry rack at waist height or higher;    2. If the material has hook and loop, separate straps so they don’t touch;    3. Hold the can approximately 6-8 inches away from the device;    4. Spray or apply the solution to all surfaces until slightly damp; DO NOT soak 5. Let the device dry completely 6. Store device in assigned enclosed storage space 7. Wash/sanitize hands. |