Harvard University

# **Detailed Guidance for Human Subject Research: [YOUR METHOD/DEVICE NAME]**

This is specific guidance for preparing, operating, and cleaning [YOUR METHOD/DEVICE NAME]. 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. [You can add/modify the introduction if there is anything worth to mention specific to the method/device.]

**Pre-Visit Screening Procedures**

* [Add here if there are tasks will be done remotely before the study visit, e.g. remote screening and/or consenting, sending an instructional video to the subject in advance, having a video chat to instruct the subject in advance, etc.]

**General Procedures**

* [Add here if there are general procedures that should be followed throughout the study visits, e.g. general precautions (e.g. washing hands), PPE, ventilation, etc. Most items that are in the example SOP should be applicable for most human subject research, so you can just copy them. You can also add or modify based on your specific method/device, but still following the general human subject research guidelines by Harvard.]
* [Note that, as per Phase I Human Subject Research Guidelines by Harvard, 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.]

**Specific procedures for [YOUR METHOD/DEVICE NAME]**

* Preparation
  1. [Add here detailed procedures for preparing the method/device BEFORE THE SUBJECT’S ARRIVAL. This may include preparing the testing site, marking the spaces for the participant and the study team members, taking the testing materials out and cleaning them once again before usage, turning on the devices in advance to minimize the participant’s visit time, etc.]
* Operation
  1. [Add here detailed procedures for preparing the method/device WHILE THE SUBJECT IS AT THE TESTING LOCATION, from the subject’s arrival to leave. This may include physical interaction and/or conversation with the participant, applying materials on the participant, response to emergency, etc.]
  2. [Note that, as per Phase I Human Subject Research Guidelines by Harvard, 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. During the close contact, the designated study team member wears a face shield, and continuous close contact is strictly limited to 15 minutes. All possible circumstances of close contact and their duration should be clearly outlined and marked in red.]
* Cleaning
  1. [Add here detailed procedures for cleaning and sanitizing the method/device AFTER THE SUBJECT’S LEAVE. This may include dispose single-use materials, cleaning/sanitizing the non-disposable items, storing the cleaned items, logging usage/cleaning history, quarantine materials for a period of time if necessary/applicable, etc.]
  2. [Note that, as per CDC recommendation, when cleaning/sanitizing, study team members wear disposable gowns and sterile gloves. For cleaning materials, check [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.]

**Additional Considerations**

[Add here if there are any additional issues to consider that do not fall under the category above. For example, for groups working on human locomotion, additional considerations regarding the type of activity/testing, e.g. treadmill walking, over-ground walking, free motion, etc., have been added here.]

**References**

[Add here if there are any references to support the safety of the procedures outlined above.]