Harvard University

# **Detailed Guidance for Human Subject Research: Wearable Robots, Sensors, and Textiles**

This is specific guidance for preparing, operating, and cleaning wearable robots, sensors, and textiles. 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 Wearable Robots, Sensors, and Textiles**

* Preparation
	1. One person prepares and sets up the actuator, the controller, the data logger, textile components, shoes/boots, and/or wearable sensors.
* Operation
	1. Before the data collection, the designated study team member makes close contact with the participant for up to 15 minutes to don the exosuit and put the sensors and connect the cables. This may involve touching the participant’s skin.
		1. If appropriate for study design, participants may don certain components 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 10 minutes to adjust the exosuit components or to replace the battery for the mobile actuators.
	3. After the data collection, the designated study team member makes close contact with the participant for up to 5 minutes to disconnect the cables. Then, if possible, the participant doffs the suit by themselves to minimize close contact.
* Cleaning
	1. When cleaning, study team members wear disposable gowns and sterile gloves per CDC recommendation.
	2. For machine washable items, the study team either (i) washes them using a designated washing machine or (ii) uses laundry service. Detailed step-by-step procedures are as follows:

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| **Machine Washing** | **Laundry Service** |
| When finishing a testing,1. Wash hands;
2. Don personal safety equipment - mask and gloves;
3. Machine wash warm with detergent;
4. Machine dry- high temperature;
5. Sort and fold laundry;
6. Return to enclosed storage space;
7. Wash hands.
 | When finishing a testing,1. Wash hands;
2. Don personal safety equipment - mask and gloves;
3. Bundle laundry in disposable bag;
4. Take bag to assigned no-contact pick up point for laundry service;
5. Wash hands.

When laundry is returned,1. Wash hands;
2. Don personal safety equipment - mask and gloves;
3. Pick up bag at no-contact exchange point;
4. Return to enclosed storage space;
5. Wash hands.
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* 1. For porous and/or non-washable items, a study team member cleans and sanitizes the materials following detailed step-by-step procedures:

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| Using Lysol Disinfecting Wipes/Spray or equivalent,1. Wash hands;
2. Don personal safety equipment- mask and gloves;
3. Lay/hang the device out on a laundry rack at waist height or higher;
4. If the material has hook and loop, separate straps so they don’t touch;
5. If the material has BOA, pop the BOA dial; pull the Spectra cord to its full extension and lay it flat; Do not dis-assemble;
6. Hold the can approximately 6-8 inches away from the device;
7. Spray or apply the solution to all surfaces until slightly damp; DO NOT soak
8. Let the device dry completely;
9. Store device in assigned enclosed storage space;
10. Wash hands.
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**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.
* Indoor overground testing
	+ The lab space should be divided into the participant's space (e.g. the overground walking path) and the study team members’ space, with any necessary close contact only occurring at the boundary. At least 6 ft must separate the participant 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 spaces 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.
		- In case of changing settings inside of the participant’s space during the study visit, the study team asks the participant to move away from the testing space so that the designated study team may enter the participant’s space while still maintaining 6 ft distancing.
	+ 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.
* Outdoor overground testing
	+ The study team should check their own IRB-approved protocol for safety procedures for outdoor testings, e.g. the minimum number of study team members present, presence of CPR-trained members, etc.
	+ The study team selects relatively less crowded IRB-approved testing sites/routes, such as Middlesex Fells Reservation (4 Woodland Rd, Stoneham, MA 02180) or Mount Auburn Cemetery (580 Mt Auburn St, Cambridge, MA 02138), and testing should be scheduled avoiding the location’s popular times.
	+ Sealable containers should be used for transporting materials and devices. After testing, uncleaned materials are packed in sealed containers and brought back to a designated space for handling and cleaning these materials, e.g. motion capture lab. When cleaning, the containers used for transporting uncleaned materials should also be cleaned and sanitized using Lysol Disinfecting Wipes/Spray or equivalent.
	+ Except for the close contact instances outlined above, all study team members and the participant should keep 6 ft distance throughout the testing. Whenever possible, keep adequate distance from other pedestrians as well, e.g. to stop and wait until other pedestrian(s) to pass by.
* General fit and sizing test
	+ Two people, one participant and one study team member or two study team members, are present.
	+ The two people separate out maintaining 6 ft distance. The participant (or a study team member) dons the device to be reviewed while the other maintains a 6 ft distance. Device review through discussion of fit, sizing, and actuation will be done from 6 ft apart, then close contact with the lab member for up to 5 minutes may occur to interact with the device on the person. This interaction-and-review process can be repeated up to 3 times per a visit.
* Testing with populations that require clinical oversight
	+ For IRB approved protocols that require clinical oversight (i.e. the presence of a Physical or Occupational Therapist), at the discretion of the clinician an additional researcher may need to be in close contact with the participant during certain activities where a clinical guard is required for safety. For example, when a researcher must don a device while the participant is standing, a Physical Therapist may be within six feet of the participant for stand-by assistance in case of balance issues.