



COVID-19 Human Subject Research (HSR) Standard Safety Plan

Instructions

This plan can be used to conduct in-person HSR if you can follow all elements of this plan:

- **New studies:** reference this plan in your study protocol and wait for IRB approval.
- **Existing studies wishing to resume in-person research:** add a comment to your study dashboard to indicate that you are restarting research following this plan.

If you are **NOT** able to follow all elements of this plan, develop a **COVID-19 Human Subject Research (HSR) Study-Specific Safety Plan** that includes the safety steps you will take and also how you will address the elements below that you are not able to follow.

Plan Contents

- **Before Subject Arrival**
 - When scheduling appointments for human subjects, instruct subjects to call ahead and discuss with them the need to reschedule their appointment if they develop fever or symptoms of COVID-19 on the day they are scheduled to be seen.
 - Advise human subjects, as well as anyone accompanying the human subject, of all procedures concerning their visit and that they all must wear cloth face coverings before entering the facility. Ask the participant if he or she will need a face covering provided or if they will bring their own.
 - Advise subject of the location of parking lot to be used and the entry point to the building that they will use. For research locations other than UCF facilities, provide adequate directions for the subjects to arrive at the location.
 - Provide a copy of “Important Information about COVID-19 and Research Participation” to the research subjects. This information contains a list of medical conditions that increase the risk for developing serious COVID-19 illness so that they can decide whether to participate.
 - Advise the subjects of the check-in and screening procedures to be used:
 - The day before the visit, contact the subject to conduct a verbal health screening over the phone. You do not need to document the specific answers, only that the screening took place.

Health Screening Questions for Participants:

1. **IN THE PAST 24 HOURS**, have you had any of the following symptoms? **YES** **NO**
 - Fever
 - Cough
 - Sore throat

- Shortness of Breath
- Loss of smell or taste
- Chills or repeated shaking with chills
- Muscle fatigue
- Headache
- Nausea, vomiting, or diarrhea
- Congestion or runny nose

If “YES”, **DO NOT participate in this study.**

2. Have you **TRAVELED INTERNATIONALLY** in the past 14 days? **YES NO**

If “YES”, **DO NOT participate in this study.**

3. Have you **TRAVELED DOMESTICALLY (U.S)** to areas of high COVID-19 prevalence (e.g., New York City, South Florida, etc.) in the past 14 days? **YES NO**

If “YES”, **DO NOT participate in this study.**

4. Have you had **CLOSE PERSONAL CONTACT** with anyone who has been diagnosed with COVID-19 in the past 14 days (per criteria below)? **YES NO**

a. Within 6 feet for prolonged period of time

b. In direct contact with infectious secretions (been coughed/sneezed upon, etc.)

If “YES”, **DO NOT participate in this study.**

Upon Subject Arrival and During the Visit

- Limit and monitor points of entry to the facility.
- Advise subjects and visitors entering the facility to put on a cloth face covering or facemask before entering the building and await screening for fever and symptoms of COVID-19.
- Maintain 6 ft separation between all individuals associated with the HSR activities at all times.
 - Maintain 10 ft separation between all individuals associated with HSR activities that involve physical exertion.
- Sanitize all touch points and research-related equipment before and after use following CDC guidelines.
- Do not ask subjects to ingest food, liquids, medications, supplements, etc.
- Take steps to ensure everyone adheres to respiratory hygiene and cough etiquette, hand hygiene, and all human subjects and visitors follow the procedures throughout the duration of the visit.
 - Post [visual alerts](#) (e.g., signs, posters) at the entrance and in strategic places (e.g., waiting areas, elevators, cafeterias) to provide instructions (in appropriate languages) about hand hygiene, respiratory hygiene, and cough etiquette.

Instructions should include wearing a cloth face covering or facemask for source control, and how and when to perform hand hygiene.

- Provide supplies for respiratory hygiene and cough etiquette, including alcohol-based hand rub (ABHR) containing 60-95% alcohol, tissues, and no-touch receptacles for disposal, at facility entrances, waiting rooms, and human subject check-ins.
 - Consider establishing screening stations outside the facility to screen individuals before they enter.
 - Ensure that, at the time of subject check-in, all visitors and subjects are asked about the presence of fever, symptoms of COVID-19, or contact with patients with possible COVID-19.
 - Refuse access to individuals with symptoms of COVID-19 and advise they contact their health care provider for advice and follow-up care.
 - Review local, state, and national public health agencies advisories and incorporate questions about new onset of COVID-19 symptoms into daily screening as they become identified by the public health officials.
- **Additional Strategies to Minimize Chances for Exposure:**
 - Implement alternatives to face-to-face visits.
 - Consider suspending group activities (e.g., group therapy or other group activities) until circumstances permit.
 - Justify the need for in-person focus groups (why not remote?)
 - Postpone all non-essential activities until circumstances permit