

Resuming In-Person Human Subjects Research (HSR)

6/16/2020



UCF

Our Goal: Keeping everyone as safe as possible, while increasing research activity in a phased approach as safety becomes easier to maintain.

HSR Remote Research

- If you can conduct your Human Subject Research remotely, do so until circumstances permit. The policy can be found [here](#)
- Protocol changes necessary to accommodate remote research for Expedited and Full Board studies **must** be reported via a study modification in Huron IRB.
- Continue to conduct your study remotely, but the modification must be submitted to continue research remotely by 7/15/2020.
- Continued remote research for Exempt studies **should** be reported via a study modification in Huron IRB.
- If it is not possible to conduct your research remotely, the following slides will help you restart your in-person research

Do You Need to Resume In-Person HSR?

Resuming in-person HSR will require safety measures; there are two paths your in-person research could take:

- Procedures allow you to follow COVID-19 HSR [Standard Safety Plan](#)
- You are not able to follow all elements of the Standard Plan, therefore a COVID-19 HSR [Study-Specific Safety Plan](#) is needed
- See the next slides for an overview of the decision process, details follow

IF CONDUCTING REMOTE HUMAN SUBJECT RESEARCH (HSR) IS NOT POSSIBLE, CAN I RESUME RESEARCH IN-PERSON?

Are your study participants part of a COVID-19 vulnerable population? ([see CDC definition](#))

NO

YES

During study procedures, are you able to maintain greater than 6 feet of distance from your subjects the entire time? Or 10 feet for procedures involving heavy exertion? This includes providing/affixing participant's equipment.

YES

NO

Will your research prohibit the participant or researchers from wearing a face covering (for example, must they wear a measurement device for cardiorespiratory testing)?

NO

YES

Can you sanitize surfaces touched by participants or researchers between participants? Examples- devices, furniture, etc.

YES

NO

Will your participants be asked to ingest food, liquids, medications, supplements, etc. as part of your research?

NO

YES

SUBMIT AN HSR COVID-19 [STUDY SPECIFIC SAFETY PLAN](#) FOR REVIEW PRIOR TO RESUMING HUMAN SUBJECT RESEARCH

FOLLOW THE HSR COVID-19 [STANDARD SAFETY PLAN](#)



UCF

Overview

- If you can continue remote research, do so but modify your study by 7/15/2020.
- If you can follow the COVID-19 HSR [Standard Safety Plan](#) add a comment to your study, request permission from your Associate Dean for Research using the standard email, and then resume in-person research, more details in following slides,
- If a COVID-19 HSR Study-Specific Safety Plan is needed, modify your study and wait for IRB approval to resume in-person research, more details in following slides



Resuming In-Person Human Subject Research – Standard Safety Plan



UCF

First Steps to Resume In-Person Human Subject Research without Close Contact or High Risk

- These guidelines apply to all in-person research and are intended to protect both the researchers and the participants
- HSR with close contact and/or high-risk participants will have additional requirements,
- You **do not** need to seek IRB approval for research that follows the standard safety plan.
- However, you should notify your intent to resume in-person research by sending a comment through your study main page in Huron IRB.
- You **do** need to request approval via a standard email from your Associate Dean for Research prior to restarting HSR based on your ability to meet all requirements in the standard safety plan

Standard Email to Associate Dean for Research of your college

I would like to restart my in-person research that does not involve close contact or high-risk populations and follows the Standard Safety Plan. I affirm the following:

- My study participants are not part of a COVID-19 vulnerable population
- During study procedures, I will be able to maintain greater than 6 feet of distance from my subjects the entire time, or 10 feet for procedures involving heavy exertion? This includes providing/affixing participant's equipment.
- My participant and researchers will be able to always wear a face covering
- I can sanitize surfaces touched by participants or researchers between participants.
- My participants will not be asked to ingest food, liquids, medications, supplements, etc. as part of my research

Before You Restart Your Human Subject Research

- Have a study visit area that can accommodate physical distancing
- Reopen your laboratory or research space following the Research Ramp up process, info can be found [here](#). Your researchers must sign in and sign out of the lab as is detailed in this information.
- Complete EH&S Training prepared specifically for COVID-19. [Log in through EHS portal](#)
- Follow the [Standard Safety Plan](#) that will allow you to conduct in-person interventions
- Review the standard safety plan with all research staff involved in your study
- Submit an email to your Associate Dean for Research requesting approval for restart based on your ability to meet all requirements in the standard safety plan

Research Conducted Outside of UCF Facilities

- Research conducted in external clinics and other established institutional settings (schools, prisons) – external institution policy prevails
- Research in non-institutional/community settings – must follow most [recent community/state policy and guidelines](#)

Before Participants Arrive

- 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.
- When scheduling appointments for human subjects, instruct subjects to call ahead and discuss the need to reschedule their appointment if they develop fever or symptoms of COVID-19 on the day they are scheduled to be seen. Review the safety plan with all research staff involved in your study
- 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 (a supply of face coverings should be available in any case).

Before Participants Arrive

- 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.
- Advise human research subjects of medical conditions that increase the risk for developing serious COVID-19 illness so they can decide whether to participate (see standard safety plan).
- 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.

Before Participants Arrive - Disinfecting

- Maintain routine disinfecting processes in labs/research space
- Cleaning and disinfection should occur upon entering the laboratory, during research, and after participants leaves
- Pay special attention to high-touch areas
 - These areas have higher probability of viral loading in the work area and should be disinfected on a routine basis and immediately after use
 - Light switches
 - Door handles
 - Benchtops
 - Equipment handles and latches
 - Equipment controls and touchpads
 - Drawer and cabinet handles
 - Hand tools
 - Faucet handles and sprayer grips
 - Chair backs and arm rests
 - Pens, whiteboard markers
 - Shared computer mice and keyboards

Upon Subject Arrival and During the Visit-Screening

- Provide participant with [Important Information about COVID-19 and Research Participation](#)
- 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.

Upon Subject Arrival and During the Visit –Social Distancing

- Limit and monitor points of entry to the facility.
- Always maintain 6-ft separation between all individuals and investigators associated with the HSR activities
 - Maintain 10-ft separation between all individuals associated with HSR activities that involve physical exertion.
- Consider installing physical barriers (e.g., glass or plastic windows) at reception areas to limit close contact between personnel and human subjects.

Upon Subject Arrival and During the Visit - Respiratory Hygiene

- 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 and 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.
- Advise subjects and visitors entering the facility to put on a cloth face covering or facemask before entering the building and await to be asked about the presence of fever or symptoms of COVID-19.

Upon Subject Arrival and During the Visit-Personal Hygiene

- Personal Hygiene
 - Wash hands frequently
 - Minimally when entering and exiting laboratory
 - After touching your face
 - Use soap and water when available (Use alcohol-based hand sanitizer if no soap + water)



Need Supplies?

- Contact Emergency Operations Center at 407-882-7111. This office is coordinating supplies.
- For face coverings fill out the [request form](#) and email it to EOC@ucf.edu
- Contact Zenaida Gonzalez Kotala for more downloadable sign files
(Zzenaida.Kotala@ucf.edu)

In-Person Research Without Close Contact, Summary

- Research may resume following previous guidelines once you complete the required steps.
- You do not need to seek IRB approval if you can follow the standard safety plan, however, you do need to receive approval from your Associate Dean for Research
- Remaining information is for In-Person, **Close-Contact and/or High-Risk** Interventions



Resuming In-Person Human Subject Research – Close-Contact or High- Risk Interventions



What types of studies need a COVID-19 HSR Study-Specific Safety Plan?

- Studies that involve human subjects in a COVID-19 high-risk population ([see CDC definition](#))
- Studies that require collection of biospecimens from participants (for example; blood draws, nasal swabs, sputum, etc.) that require contact with participant
- Studies that require close contact between participants and research staff. For example: to directly hand participants a device, help them attach electrodes, perform an ultrasound measurement, examine their throat, administer a drug, ensure physical safety
- Research requiring ingestion of food, liquids, supplements, etc. by the participant as part of your protocol

Restarting Your In-Person Research with Close Contact and/or High Risk

- Follow the COVID-19 HSR Standard Safety Plan where possible
- Where not possible, create a COVID-19 **Study-Specific Safety Plan** to address steps you can take to minimize exposures
- Upload the proposed [Study-Specific Safety Plan](#) for close contact or high risk in-person research to your study on the Huron IRB portal as a modification
- IRB and Environmental Health and Safety (EH&S) staff will review the proposed safety plan, weighing the risks from COVID-19 against the study benefits, and determine whether the study can restart or should remain suspended
- **IRB approval of any such study modification is required before any in-person studies with close contact and/or high risk are permitted to resume.**

COVID-19 Populations at Heightened Risk

- For participants (or those accompanying participants) that are
 - Over 65 years of age
 - Diagnosed with chronic lung disease, or moderate to severe asthma
 - Diabetics
 - Serious heart conditions
 - Severe obesity (BMI of 40 or higher)
 - Liver disease
 - Chronic kidney disease undergoing dialysis
 - Immunocompromised: cancer treatment, bone marrow/organ recipients, chronic immunodeficiencies, poorly controlled HIV or AIDS, prolonged use of corticosteroids and other immune weakening medications)
- Researchers must:
 - Use appropriate PPE
 - Maintain proper hand hygiene

Considerations for Configuring the Physical Research Setting

- Laboratory/Research Space
 - System for one-way flow of people through the lab.
 - Proper signage.
 - Minimize staff and volunteer numbers.
 - Maintain social distancing unless wearing suitable PPE.
 - Minimize surface clutter to ease disinfection.
 - Wipe down workstations between participants and before leaving the lab (e.g. keyboards, chairs, handled equipment).
 - Require regular hand washing upon entering and leaving the research space.
 - Identify specific loading/unloading delivery areas where social distancing can be maintained but deliveries remain safe and secure.
- In the Field
 - Maintain social distancing, use PPE otherwise

PPE Guidance for In-Person HSR

| Risk Level | Example Study Procedures | Suggested PPE |
|------------|--|--|
| Low | Computer testing; use of simulators or eye trackers; collection of biological data through non-invasive means (e.g., ECG, EEG, ultrasound, blood pressure); vision tests, fitness trackers; collection of specimens where no contact with the researcher is required such as vaginal secretions and throat/nasal swabs | Facemasks for both subject and research staff; 6 ft distance if possible, gloves required |
| Medium | Exercise testing with minimal exertion; vascular testing; echocardiography; collection of biological specimens that are NOT blood, saliva or sputum such that direct contact between participant and researcher is NOT required. For example, external secretions such as sweat | Research staff closer than 3 ft wear facemask with shield; regular face covering for other staff, gloves required |
| High | Exercise Testing with maximal exertion, collection of biological specimens that include blood, saliva or sputum such that direct contact between participant and researcher is required. (e.g., blood draw, non-invasive throat and nasal swab, nasal swabs that go beyond the nares) | Consider requiring documentation of COVID testing for participants; researchers less than 3 ft wear facemask with shield; consider wearing a gown if <1 foot away, gloves required |

Guidance for Activities Where Close Physical Contact Is Necessary

- Normally, you should not breach social distancing rules to collect samples or assist participants with study activities. To do so safely would require, at minimum: lab coat, gloves and fluid resistant surgical mask, hand washing before and after the intervention.
- Contact should be quite brief. “Brief” is intended to mean something measured in minutes rather than hours.
- Example: A single venipuncture for a blood sample is acceptable, but repeated sampling during a day from an indwelling venous catheter is not considered “brief.”

Guidance for Activities Where Close Physical Contact Is Necessary

- Wear PPE relative to risk level of intervention
- Daily screening for COVID-19 risk and infection prior to contact
- Participants wait outside building
- Maintain temporal spacing between participants
- Hand hygiene before entering and exiting research area; before and after handling samples
- Physical items that participants make contact with should be decontaminated before and after each participant

Guidance for Activities Where Participants Cannot Wear Face Coverings At All Times

- Researcher must wear PPE at all time
 - N95
 - Eye protection
 - Gloves
 - Lab coat
- Minimize the time when participant's face covering is not worn
- Physical distancing must be maintained when face coverings are not worn
- Physical items that participants make contact with should be decontaminated before and after each participant
- Maintain proper hand hygiene (wash hands before and after handling samples)

Suggestions for Alternatives to Sanitizing Equipment with Ethanol or Soap/Water

- Consider using disposable plastic or paper coverings that can be changed between participants.

To Summarize

- If you can continue remote research, do so but modify your study by 7/15/2020
- If you can follow the COVID-19 HSR [Standard Safety Plan](#) add a comment to your study, request permission from your Associate Dean for Research, and then resume in-person research (refer to flow chart in slide 5)
- If a COVID-19 HSR [Study-Specific Safety Plan](#) is needed for close contact and/or high risk HSR, modify your study and wait for IRB approval to resume in-person research (refer to flow chart in slide 5)
- **Questions:** IRB@UCF.EDU

Thank You!

