

	COVID-19 Human Subject Research (HSR) Study-Specific Safety Plan		
IRB study number:		PI:	
Title:		Faculty Advisor:	

Instructions

This plan is to be used to describe additional protections needed to conduct in-person HSR where all elements of the Standard Safety Plan cannot be followed:

- **New studies:** include the study specific safety plan as part of your “other study documents” in the Huron IRB application and reference the plan in your protocol. Wait for EHS and IRB approval.
- **Existing studies wishing to resume in-person research:** create a modification to your study to indicate that you are requesting to restart research after EHS and IRB approval of the plan. Modify the protocol to reference your study specific safety plan, include the plan as part of “other study documents”, and modify the consent form to include protocol changes that involve changes to what the subject will be asked to do in addition to the standard plan elements. For example, if subjects will need to affix research apparatus instead of having study personnel affix the equipment, update the procedures in the consent form. Wait for EHS and IRB approval.

Plan Contents

1. **Describe your physical research setting.** Provide details about where the in-person research will take place — list room and building number for UCF campus facility, other institutional facilities, commercial or public spaces. Provide details about who needs to be present and an estimated number of the research team and human research subjects that would need to be present during in-person research activities at any given time.

2. **Describe the safety plan bringing the human research subject to and from the physical research setting for in-person activities.** Include advising on parking, points of entry, face covering requirement, screening procedures, hygiene and sanitation practices, scheduling to minimize social density, and rescheduling procedures.

3. **Does your research involve using COVID-19 high-risk populations? If so, what steps are you taking to protect these subjects?** Identify which high-risk population you are working with. Describe provisions to protect this population.
If you do not have high-risk populations or subjects with conditions that increase their risk, type NA.

- 4. Describe research activities that need to occur in close contact between research personnel and human research subject** (less than 6 feet apart for standard activities or 10 feet for procedures involving heavy exertion) and include the approximate time needed for each activity. What additional protections can you put in place to minimize exposures, other than the standard face covering? For example, are you using additional shielding? For studies where researchers need to affix equipment to participants, are you able to provide instructions to enable the participants?

If you can follow the physical distance requirements in the COVID-19 Standard Safety Plan, type NA.

- 5. Describe the use of face coverings and how these coverings will be supplied to research personnel and human subjects.** Explain any research activities that would be compromised from either the study personnel or human participants wearing face coverings at all times. Provide information on additional protections you can put in place to minimize exposures (for example shielding, distancing).

If you can follow the facial covering requirements in the COVID-19 Standard Safety Plan, type NA.

6. **Describe any equipment or research apparatus that a subject will handle or will be in contact with any part of their body that will be difficult to sanitize using the Standard COVID-19 Safety Plan.** What sanitizing methods can you use? Describe the methods in detail for each type of equipment (for example UV exposure for electronics, headsets). **If you can follow the sanitization requirements in the COVID-19 Standard Safety Plan, type NA.**

7. **Describe availability of critical supplies needed to conduct this study: e.g., appropriate amount of facial coverings, cleaner, sanitizer.** Do you have enough supplies to conduct this research? If not, how you do plan to obtain it?

8. **Does this research involve asking human research subjects to ingest food, liquids, drugs, supplements, etc.?** Describe how the items are supplied, for example, is this pre-packaged? What protections can you put in place to minimize the possibility of contamination?

If subjects will not be asked to ingest anything, type NA.