UCSB Stage 4b Research Ramp Up

**Participant Safety Plan for Research Activities**

**Human Subjects Research Participant Safety Plan**

Revision 2020.10.31

All faculty/PIs whose research involves in-person interaction with participants must (1) fill out this form and (2) submit this form as described in the Submission Process section at the end of this document. A copy of your approved safety plan(s) must then be submitted as an attachment to your relevant HSC/IRB protocol by submitting a modification in ORahs.

**In-person research may not commence until all of the steps of the approval process listed at the end of this document have been completed.**

## Study Information

PI Name (Last, First): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Primary Home Department/ORU: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Building: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

ORahs #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Population Risk:**

Provide a brief description of your research **subjects/participants** (e.g., including age range, student or community members, and any other information relevant to their risk level (low, moderate, high) as determined from the Risk Matrix):

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**Research Activity Risk:**

Provide a brief description of your **research activities (i.e., what will participants be doing in the study, and how will they be interacting with research staff).** Describe the risk level (low, moderate, high) of this research activity, as determined from the Risk Matrix. Ensure that it is clear how the risk level was determined:

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**Location Risk:**

Provide a brief description of the **location of research activities**. Describe the risk level (lower, moderate, higher) of this research location, as determined from the Risk Matrix:

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**Exception to Risk Level:**

If your research involves an aggregate risk level (Population + Activity + Location = aggregate risk) that is not allowed during the current Stage, please explain how you will mitigate those risks to a lower level and why you should receive an exception from the current risk level:

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My research involves (select all that apply):

[ ] in-person interaction with study participants on campus (If only on-campus, mark section 4 as “Not applicable.”)

[ ] in-person interaction with study participants in off-campus/international settings

## Participant Safety Measures

Please answer the questions below.

Once your safety plan is approved these COVID-19 safety measures must be in place until deemed no longer necessary by the University of California, Santa Barbara or in the case of off-campus research, by local public health authorities.

Please refer questions to hsr-covid@research.ucsb.edu.

### Section 1: Scheduling Coordination and Minimizing Contact

Complete for each of your assigned on-campus research spaces including laboratory spaces with an assigned density budget. *If off-campus, you don’t need to list the Building, Room #, or Density Budget, but must answer the question about scheduling and coordination of work.*

Building:

Room #(s):

Density Budget(s):

Describe your plan for scheduling and coordination of work hours among research personnel, including how they will be arranged and scheduled. Describe how participant visits will be scheduled and coordinated to limit density and ensure physical distancing. Indicate how you will quickly ramp-down the study if required to do so and coordinate with participants who are scheduled to come to campus.

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### Section 2: Workflow for Experimental Sessions

Please describe workflow for a typical experimental session. Include:

1. **Number of experimenters and participants/subjects**

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2. **Minimum distance between all individuals** (including researcher-researcher and researcher-participant; if nine feet of separation cannot be maintained at all times, describe why closer interaction is necessary)

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3. **Location, timing, and nature of interactions** (include a brief description of the activity, where it will take place, its duration, how the participants will get to and from the research location, and any signage at the facility that provides important information to both the participants and UCSB-affiliated individuals)

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4. **Facial coverings/PPE are required.** Select which of the below will apply to your research project, by placing an [x] in the relevant options:

1. [ ] Study personnel and participants wear cloth facial coverings or surgical/procedure masks during face-to-face interactions and interventions:
* The participants must respond NO to COVID-19 Screening AND
* The participants are expected to be located in or from an area or facility with no or only isolated cases AND
* The interventions do not generate aerosols AND
* At least **six** **feet** (9’ preferred) of physical distancing will be maintained at all times
1. [ ] Study personnel must wear a surgical/procedure mask and face shield during face-to-face interactions and interventions with participants who will wear a cloth facial covering or surgical/procedure mask:
* The participants must respond NO to COVID-19 Screening AND
* The participants are expected to be located in or from an area or facility with no or only isolated cases AND
* The interventions do not generate aerosols AND
* At least **six** **feet** of physical distancing will **NOT** be maintained at all times
1. [ ] Study personnel must wear an N95, face shield, and gown during face-to-face interactions and interventions with participants:
* The participant will be known or suspected to have COVID-19 OR
* The participants are likely to be located in or from an area or facility with known or a high likelihood of cases and/or transmission OR
* Study procedures will **not** allow the participant to wear a mask or face covering for an extended period of time OR
* The interventions include procedures that generate aerosols
1. [ ] Other (or more than one of the above), describe:

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5. **You must follow CDC and state guidelines for cleaning and disinfecting common touch points and equipment.** Examples of common touch points include:

* Benchtops, desktops, and other work surfaces;
* Equipment handles and latches;
* Equipment controls and touchpads;
* Office supplies (pens, pencils, etc.)
* Drawer and cabinet handles;
* Sashes of chemical safety hoods and biosafety cabinets;
* Faucet handles and sprayer grips;
* Chair backs and armrests (fabric furniture that cannot be decontaminated should not be used);
* Doorknobs and light switches;
* Keyboards, touchpads, and mice;
* Remote controls.

**You must clean and disinfect research procedure areas and data collection areas, using an** [**EPA-registered cleaning product**](https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2) **or a 70% alcohol solution prior to and following use by participants or study personnel.** This will include a regular wipe down of shared research equipment and spaces (e.g., desktops) after each participant visit, plus a wipe down of shared research equipment and spaces at the end of the day. If participants wish to also wipe down apparatus, they must be provided with disinfectant wipes and encouraged to wear gloves when using them. Please note that any cleaning done by participants does not substitute for the required cleaning by study personnel. If participants are using keyboards, study personnel should put a smooth covering over them. Participants using a shared piece of equipment should also be offered hand sanitizer containing at least 60% alcohol and gloves for optional use during the visit. Participants who choose to wear gloves should be provided with instructions on how to remove and dispose of gloves safely. Hand sanitizer should be available to participants throughout their study visit.

Used gloves, facial coverings, PPE, coveralls, etc. should be placed in a lined container, preferably with a lid/cover. Tightly close off the bag before disposing the solid waste items into the solid waste bin for pickup by the solid waste management company. Wash your hands with soap and water for 20 seconds (preferred) or alcohol-based hand sanitizer immediately after handling these items.

**Describe any additional strategies for mitigation (i.e. wearing gloves, contactless temperatures taken, assuring adequate ventilation, physical barriers, and additional disinfection).**

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**Describe any equipment or areas that cannot be disinfected daily using an** [**EPA-registered cleaning product**](https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2) **or a 70% alcohol solution, and steps that will be used to prevent transmission** (e.g., covering instruments with plastic).

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**Describe any items or devices (e.g., virtual reality headsets, computer, tablet, or a sensing or measuring device, etc.) that will be shared between or used by more than one participant and the steps that will be used to disinfect the device to prevent transmission.** Extraordinary care should be taken to disinfect these items. Explain how many participants will have access to these items, and the rationale for sharing the same item with multiple participants.

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6. **Do research participants spend time in a waiting area? How will public health precautions be maintained in such spaces?** (e.g., seating has been arranged or modified to meet physical distancing requirements)

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7. **Are you using any shared spaces that are also in use by other research groups?** Explain how many people have access to such spaces at any one time and how hygiene and social distancing will be maintained.

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### Section 3: Screening of Human Subjects for COVID-19 Infection

Please explain how you will screen subjects for symptoms of COVID-19 infection, manage screening data, and pre-inform subjects of this screening. We strongly recommend using the template Participant Symptom-screening Survey & Information Sheet at the end of this document. *The research team shall comply with campus symptom-screening requirements or those required by your Building Committee.*

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### Section 4: Off-campus Research (domestic or international)

For research performed off campus (either within state, within the US, or internationally), please state the location(s) and explain the current local public health regulations. Attach any documentation about the safety requirements at the off-campus facility or letters of approval. Explain a typical participant interaction and how it will conform to local requirements. Please incorporate answers to the questions listed in Sections 2 & 3, unless there is a compelling reason not to do so.

*Note: Research that takes place off campus will also require review by the Off-Site Research Committee. If your research involves both off campus research and in-person components, your Building Committee should direct you to complete both this Participant Safety Plan and the* [*COVID-19 Field Safety Plan*](https://docs.google.com/document/d/1WRr98xYYJ8zwfzpEeBd-uWsC3ibXS4dln38yCWQ4Puc/edit)*.*

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### Section 5: Attestation

By submitting this form,

I confirm that I:

* Have reviewed the Office of Research COVID-19 [guidelines](https://docs.google.com/document/d/1bbd4EVzdx1TSEnRVAhAvrLAfcO3_1ICM_qq1H85Yrw0/edit?usp=sharing) and completed any UCSB required COVID-19 safety training, and am familiar with the current [Orders of the State Public Health Officer](https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Immunization/ncov2019.aspx) in California (or relevant local authority), and believe my proposed plan is in compliance.

I confirm that all of my lab group members:

* Have received a copy of this Participant Safety Plan, read it in full, and been given the opportunity to ask questions and/or voice any concerns.
* Understand the process for scheduling participant visits, and the occupancy limits for the areas in which this research will occur, including human subjects participants.
* Have completed any UCSB required COVID-19 safety training that they have been requested to take

I confirm that my lab will:

* Develop a process that ensures symptom-screening of all participants coming for in-person interaction and that lab members will be trained on the plan.
* Develop a process to conduct dry runs of this safety plan, which will be conducted prior to scheduling participant visits.
* Establish a process to monitor compliance with this safety plan and to document and promptly correct deficiencies.

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Signature (ink or electronic) *Do not sign until requested to do so.*

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Name (type)

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Date

### Resources

[Office of Research COVID-19 webpage](https://www.research.ucsb.edu/office-research-mission-continuity-plan)

[Ramp-up Stage Definitions & Criteria](https://docs.google.com/document/d/1SIv6RGWR_MX3DgiroJrPctA8iXWZ6TsWQ2JrenIXSMg/edit#heading=h.ppl8p4xi97fb)

[Guidelines for Minimizing Risks](https://docs.google.com/document/d/1bbd4EVzdx1TSEnRVAhAvrLAfcO3_1ICM_qq1H85Yrw0/edit)

[Office of Research Integrity COVID-19 webpage for human subjects research](https://www.research.ucsb.edu/human-subjects/covid-19-impact-human-subjects-research)

[CDC Guidance for Colleges and Universities](https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/index.html)

[California Department for Public Health Guidance for Colleges and Universities](https://covid19.ca.gov/education/#top)

### Submission and approval process

Instructions for completing form in Google Docs:

1. Make a copy. Go to File → Make a copy → Rename → Select folder to save copy
2. Complete form and save
3. Email completed form as Google Doc to BOTH your Building Committee and Participant Safety Committee at hsr-covid@research.ucsb.edu
	1. Click on Google Drive icon → locate file → click on Insert
4. **Note**: For off-site research, the Building Committee will determine if the research must also be reviewed by the Off-site Research Committee. If the research requires Off-site Research Committee review, a separate form will be required to be reviewed.
5. Respond to any requests for clarification or changes to this form. These requests may come from your Building Committee, the Off-site Research Committee, or the Participant Safety Committee.
6. Once you receive Building Committee approval, upload a copy of this approval and the approved COVID-19 safety plans to the HSC/IRB through [ORahs](https://www.research.ucsb.edu/human-subjects/orahs). You may do this by submitting a modification request for an existing ORahs protocol, indicating that the modification is to resume in-person research, and attaching the required documentation, or by submitting a new study application for HSC/IRB review.
7. **You may not commence any human subjects research described above until approved by both your building oversight committee and HSC/IRB.** The HSC will notify you if additional HSC/IRB review is needed, or if you are approved to resume the research described in your ORahs protocol and associated approved safety plan(s).

**Participant Information Sheet: COVID-19 Information**

**Consider Your Risk of Exposure Before Participating**

Certain categories of individuals (e.g., immunocompromised individuals, adults aged 65 or older, etc.) may be at higher risk from COVID-19. Consider your own risk level and the risk to those in your home prior to agreeing to participate. For more information, visit the CDC website at <https://www.cdc.gov/coronavirus/>

**Self-Screening Prior to Arrival at Study Visit**

[*If your approved self-screening procedures for participants ARE DIFFERENT than the UCSB campus screening procedures, modify the section below*]

You will be asked to conduct a self-screening on the morning of the scheduled visit by answering several questions about your study visit including questions pertaining to your health related to COVID-19. The screening will take approximately one minute.

* If you answer “no” to all the self-screening questions, you can proceed with the scheduled visit.
* If you answer “yes” to any of the self-screening questions, please contact the researcher to reschedule the visit to a future date.

**Day of Study Visit Procedures**

[*If the study visit procedures ARE DIFFERENT, modify the section below*]

You will be asked to limit the number of individuals who attend the study visit with you. If necessary, any accompanying individuals will be required to wait outdoors in a designated area and wear a mask or face covering.

On the day of your study visit, we will ask you to do a number of things including:

* Call the researcher when you arrive at the destination. You will be provided instructions on where to meet the research team to enter the facility.
* You may be asked to confirm completion of the COVID-19 symptom self-screening survey before or when you arrive for your scheduled visit.
* Wear a face covering or face mask at all times, unless specifically directed;
* Avoid touching your face, mouth, or eyes whenever possible;
* Maintain 9 ft of separation between yourself and the researcher whenever possible;
* Exit the facility upon completion of the study visit accompanied by a research team member.

**Positive COVID Results Reporting**

If a research team member tests positive for COVID, we will follow local public health requirements for reporting positive test results.

**Confidentiality**
Your responses to the self-screening questions will never be stored or used for research purposes. The research team will follow the UCSB standard COVID-19 Screening Program Privacy Practices. For more information on these privacy practices visit: <https://www.privacy.ucsb.edu/covid-19>

**Questions**

[*State who the participant may contact for questions about the screening or study visit*]

You may contact the researchers at XXX for questions or concerns about the screening or study visit procedures.

**Participant Self-Screening Checklist**

Please complete this self-screening checklist at home the morning of your scheduled study visit. You will also be asked to confirm if you have completed the tool once you arrive for your study visit.

☐Yes ☐No In the last 14 days, have you had any of the following new, unexplainable, or unusual symptoms?

* Fever of 100.4F(380C) or above
* Shaking chills
* Cough
* Shortness of breath or difficulty breathing
* Loss of taste or smell
* Sore throat
* Fatigue or generally feeling unwell
* Muscle or body aches
* Headache
* Nasal congestion, runny nose, and/or sneezing
* Nausea or vomiting
* Diarrhea or loose stool
* Eye redness, with or without discharge
* Body skin rash

☐Yes ☐No In the last 20 days, have you been diagnosed with COVID-19?

☐Yes ☐No Within the last 14 days, have you had direct close contact\* with anyone known or suspected to have COVID-19 without wearing proper personal protective equipment\*\*?

If all responses are “NO”, then you are eligible for the study visit.

If you responded “YES” to any of the above, please cancel and reschedule the study visit and contact your healthcare provider if you are experiencing COVID-like symptoms.

\*Direct close contact is defined as being less than 6 feet from someone else, for a duration of 15 or more minutes

\*\*OSHA recommended personal protective equipment (PPE) for healthcare workers includes gloves, gowns, eye/face protection such as goggles or face shields, and respirators (N95 or FFP2 standard, or equivalent).