



Safety Guidelines If Proposing to Return to In-Person Research During the SARS-CoV-2 (COVID-19) Pandemic

Impact Level	IRB requirements for in-person research	Daily startup requirements	*Density of personnel (only if multiple personnel)	Personal Protective Equipment (PPE)	Disinfection	Screening of personnel	Travel	Remote contact
RED Stay at Home (Major Disruption)	Pause all in-person human research (unless essential - clinical). Convert to remote interaction if possible.	Clinical research only (essential) - Pre-screen personnel and participants in advance and at meeting.	Clinical research only (essential) - <10% of normal in-person personnel levels	Clinical research only (essential) - Face shields and gowns for personnel; face shields for participants.	Clinical research only (essential) - Prior and after each appointment.	Personnel and participants immediately before activity; phone screen 24 hours in advance.	None	Mandated whenever possible. Submit a modification application.
ORANGE Safer at Home (Moderate Disruption)	Remote interaction if possible. Limited in-person with Safety Plan submitted via Modification.	Approved in-person research: Pre-screen personnel and participants in advance and at presentation	10-25% of normal in-person personnel levels. Strict maintenance of 6 feet distancing.	Face shields and / or masks for personnel and participants; gowns for personnel (biologic contacts only)	Prior and after each interaction. Waiting areas and common spaces hourly.	Personnel and participants immediately before activity.	Approved in-person research: To remote sites as needed for essential clinical purposes only.	Mandated whenever possible. Submit a modification application.
YELLOW Act with Care (Minor Disruption)	Remote interaction if possible. Submit a modification application with safety plan if in-person.	Pre-screen personnel and participants in advance and at presentation	25-50% of normal in-person personnel levels. Strict maintenance of 6 feet distancing.	Face shields and /or masks for personnel and participants; gowns for personnel (biologic contacts only)	Prior and after each appointment. Waiting areas and common spaces hourly.	Personnel and participants immediately before activity.	Approved in-person research: To remote sites as needed.	Encouraged whenever possible
GREEN Recovery (Minimal Disruption)	Remote interaction if possible. Submit a modification application with safety plan if in-person.	Screen personnel daily.	50-75%. 6 feet distancing in rooms and waiting areas.	Face shields and/or masks for personnel and participants recommended.	Prior and after each appointment. Waiting areas and common spaces hourly.	Self-monitor for symptoms	Approved in-person research	Encouraged whenever possible
BLUE Post COVID-19 Pandemic (Limited Disruption)	With IRB approval. Vaccine in place.	Personnel self-screen.	75-100% - Post COVID-19 pandemic	Face shields and/or masks may be optional.	Prior and after each appointment.	Self-monitor for symptoms	Approved in-person research	Encouraged whenever possible.

We are Here

*Density refers to the number of research personnel in a research space, which may not be relevant for smaller research teams.
 - Adhere to UH vaccination, testing, social distancing, and PPE requirements. Please see the final page for links.
 - Report Unanticipated Problems immediately by sending an email to uhirb@hawaii.edu. Mahalo!

Safety Guidelines if Proposing to Return to In-Person Research During the SARS-CoV-2 (COVID-19) Pandemic

RED

Phase 1: “Stay-at-Home” – *Very low in-person density; (<10% of normal in-person personnel levels)*

During Phase 1, pause **all** in-person human research (unless essential - clinical). Convert to remote interaction if possible. Only two forms of human research are allowed:

- With IRB approval, therapeutic clinical trials (drug, device, or behavioral), including SARS-CoV-2 research, where there is **potential for direct benefit** to the participant and risk of viral exposure can be minimized.
- Human research **can be conducted remotely**. Submit a modification application to revise protocol to remote interaction.

The determination of whether or not research has the potential for direct benefit to the participant is made by the Principal Investigator of the research study, the participant, and where possible the participant’s care provider. This approach recognizes that the impact of clinical and other human research on a participant’s health is a medical decision that best rests with the health care team.

All human research conducted in Phase 1 must be performed in a manner which minimizes risk to participants and research personnel. This includes:

- All human participant research activities that can be performed remotely must be performed remotely.
- Adherence to UH screening protocols inclusive of daily completion of symptom tracking for all in-person research personnel and screening of study participants for COVID-19 symptoms in advance of visit and upon arrival. Screening of remote study participants is not required.
- Cleaning and disinfecting of all surfaces that either the participant or research personnel had contact with at the beginning of the day, in between each participant interaction, and at the end of the day. [CDC Guidance for Cleaning and Disinfecting](#)
- Adherence to UH vaccination, testing, social distancing, and face covering requirements. Please see page13 for more information. Mahalo.

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ORANGE

Phase 2: “Safer at Home” Minimal additional onsite and in-person research allowed - Low onsite density; (10-25% of normal in-person personnel levels)

During Phase 2, in-person human research is paused or converted to remote interaction if possible. In addition to the forms of human research allowed in Phase 1, in-person research where risk can be mitigated to a minimal risk level is now allowed with the submission of the **Safety Plan Form** via a Modification Application.

- The Safety Plan Form covers all five phases, therefore requiring only one Modification Application and Safety Plan Form.

The forms of human research allowed in Phase 2 are:

- Therapeutic clinical trials (drug, device, or behavioral), including SARS-CoV-2 research, where there is **potential for direct benefit** to the participant and risk of viral exposure can be minimized.
- Human research that **can be conducted remotely**.
- In person human research **where risk can be mitigated, as demonstrated in the Safety Plan Form**. Submit a Modification Application with the **Safety Plan Form**.

All human research conducted in Phase 2 must be performed in a manner which minimizes risk to participants and research personnel. As studies allowed to occur in Phase 2 but not in Phase 1 are likely to be performed in non-clinical facilities, adherence to the risk mitigation strategies below will be more challenging and require detailed planning and effort on behalf of research personnel. Required risk mitigation strategies are:

- All human participant research activities that can be performed remotely must be performed remotely.
- Adherence to UH screening protocols inclusive of daily completion of symptom tracking for all in-person research personnel and screening of study participants for COVID-19 symptoms in advance of visit and upon arrival. Screening of remote study participants is not required.
- Cleaning and disinfecting of all surfaces that either the participant or research personnel had contact with at the beginning of the day, in between participant interaction, and at the end of the day. [CDC Guidance for Cleaning and Disinfecting](#)
- Adherence to UH vaccination, testing, social distancing, and face covering requirements. Please see page13 for more information. Mahalo.

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YELLOW

Phase 3: “Act with Care” Additional onsite research personnel allowed – *Low-medium onsite density; {25-50% of normal on-site personnel levels (timing of transition to Phase 3 is difficult to predict, but may be feasible within 1-2 months of entry into Phase 2)}*

During Phase 3, the same forms of in-person human research allowed in Phase 2 may continue, however, minimal additional research personnel in non-participant facing roles are allowed to return onsite. Plans must be developed and implemented to ensure onsite research personnel does not exceed maximum allowable capacity or the maximum capacity where appropriate risk mitigation strategies can be implemented. P.I.s should refer to UH guidance on return to work safety and consult with their unit and campus Environmental Health and Safety Office.

- To return to in-person research, submit a Modification Application with the **Safety Plan Form**.
- The Safety Plan Form covers all five phases, therefore requiring only one Modification Application and Safety Plan Form.

If conducting off-site research, consult with the off-site research location to comply with their requirements.

Systems may be developed to rotate onsite and remote research personnel provided shared workspaces are disinfected between use and appropriate social distancing can be maintained. As in previous phases, the risk mitigation strategies outlined below must continue to be adhered to, not only in offices and other workspaces but in common spaces such as elevators, hallways, restrooms, and breakrooms.

- All human participant research activities that can be performed remotely must be performed remotely.
- Adherence to UH screening protocols inclusive of daily completion of symptom tracking for all in-person research personnel and screening of study participants for COVID-19 symptoms in advance of visit and upon arrival. Screening of remote study participants is not required.
- Cleaning and disinfecting of all surfaces that either the participant or research personnel had contact with at the beginning, in between participant interaction and at the end of the day. [CDC Guidance for Cleaning and Disinfecting](#)
- Adherence to UH vaccination, testing, social distancing, and face covering requirements. Please see page13 for more information. Mahalo.

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GREEN

Phase 4: “Recovery” Near-post SARS-CoV-2 (COVID-19) pandemic research phase – *Medium-normal onsite density; (50-75% of normal on-site personnel levels)*

Phase 4 represents additional research personnel on-site and an increase in in-person interaction research. In Phase 4, almost all forms of human research are allowed (except for those populations vulnerable to the virus), including:

- Therapeutic clinical trials (drug, device, or behavioral), including SARS-CoV-2 research, where there is **potential for direct benefit** to the participant and risk of viral exposure can be minimized.
- Human research that **can be conducted remotely**.
- In person research **where risk can and cannot be mitigated** to a minimal risk level. Submit a Modification Application with the **Safety Plan Form**.
- The Safety Plan Form covers all five phases, therefore requiring only one Modification Application and Safety Plan Form.
- Cleaning and disinfecting of all surfaces that either the participant or research personnel had contact with at the beginning, in between participant interaction and at the end of the day. [CDC Guidance for Cleaning and Disinfecting](#)
- Adherence to UH vaccination, testing, social distancing, and face covering requirements. Please see page13 for more information. Mahalo.

While in Phase 4, human in-person interaction research is allowable (not including vulnerable populations), provided all remaining government and institutional risk mitigation policies are complied with. Researchers are encouraged to maintain a balance between onsite and remote work.

Safety Guidelines if Proposing to Return to In-Person Research During the SARS-CoV-2 (COVID-19) Pandemic

BLUE

Phase 5: “Post COVID-19 Pandemic” Defining post SARS-CoV-2 (COVID-19) pandemic research phase – Near to Full onsite density; {75-100% of normal *on-site personnel levels (timing of transition to Phase 5 may not occur for months and will likely be dependent on evidence that a future resurgence of the SARS-CoV-2 pandemic is unlikely.)*} Phase 5 represents post SARS-CoV-2 (COVID-19) pandemic research personnel on-site and in-person interaction research with all populations, including in-person meetings with multiple individuals. In Phase 5, all forms of human research are allowed with all populations.

While in Phase 5, full density is allowable with all participant populations, provided all remaining government and institutional risk mitigation policies are complied with. UH understands that recovery from the SARS-CoV-2 pandemic may require a new way of being post SARS-CoV-2 (COVID-19) pandemic.

The new way of being post SARS-CoV-2 (COVID-19) pandemic will very likely require consistent vigilance over time. These guidelines will be updated when more information is available.

Safety Guidelines if Proposing to Return to In-Person Research During the SARS-CoV-2 (COVID-19) Pandemic

- Guidelines are subject to change as we move through the various phases of safely returning to in person research. Since human research includes components of both care and research, the guidelines related to the phases above are a collaboration of the UH System Human Research Protection Program (HRPP) and the Institutional Review Boards (IRBs).
- P.I.s will be required to submit a Modification application with the **Safety Plan Form** to return to in-person research. The Safety Plan Form covers all five phases, therefore requiring only one Modification Application and Safety Plan Form.
- The IRB will continue to protect populations at higher risk for severe illness from SARS-CoV-2 (COVID-19) by limiting research with these populations (i.e. older people (Kupuna), people with severe underlying medical conditions – refer to [CDC guidelines](#) for complete list of high risk people). In the safety plan, describe the screening plan for these populations.
- In-person human research must be phased-in gradually so that population densities and safe practices can be monitored to minimize risk and to ensure research team and participant health and safety.
- Research personnel in the high risk category should be given special consideration to work remotely. Safely returning to in-person research will occur in five phases as outlined above. Consider remote contact for aspects of research that do not require in-person interaction.
- There is a minimum of 14 days of observation by the HSP and IRB between decision points before moving to the next impact level.
- An undesirable trajectory of the pandemic, the appearance of SARS-CoV-2 infection of research personnel or participants, and/or evidence of significant non-compliance with the directives outlined below could lead to a return to earlier, more restrictive phases.
- Research location start-up and utilization should be coordinated with and approved by Department Chair or Dean/Director, as appropriate.
- Throughout the phased safely returning to in-person research, risk and potential benefit to participants must be balanced, while implementing appropriate risk mitigation strategies.
- Resumption and/or expansion of in-person research from the current phase (see table above) will occur slowly and will be a balancing act between ensuring access to in-person research with the potential for direct benefit to participants and ensuring the health and safety of all involved.
- In addition to the details included in this document, all general UH guiding principles and general policies must be adhered to.
- Please follow the newest guidelines as communicated by UH, federal, and local governments. Please see the final page of these guidelines for more information. Mahalo.

Navigate Content

→ Please click below to navigate directly to the topic of interest. Mahalo.

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- **Steps to Minimize Personnel Density, Allow Distancing, and Reduce the Chance of Transmission**
- **Remote Consent and Assent Considerations**
- **Remote Participant Recruitment Considerations**
- **How Information Will Be Communicated from the UH Human Research Protection Program (HRPP) and IRB**
- **Connecting with Other Researchers Conducting SARS-CoV-2 (COVID-19) Pandemic Research**
- **Research Taking Place Outside of the United States**
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- **Remote Research Technology Considerations**
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Safety Guidelines if Proposing to Return to In-Person Research During the SARS-CoV-2 (COVID-19) Pandemic

Participant Pre Screening Guidelines and Checklist

All participants attending a scheduled appointment for research related purposes must be pre-screened via telephone prior to their interaction. Using the pre-screening checklist below, if the participant answers “No” to all questions, the in-person interaction may proceed.

This pre-screening process applies to all research with human participant volunteers across the UH System. Research teams must be aware of and comply with policies and strategies for vaccination, testing, safe social distancing and PPE utilization. Current scientific understanding of transmission involving long latency (the time between exposure and symptoms), maximum infectivity right before and around the presenting of symptoms, varying symptoms among symptomatic patients, breakthrough infections and contagion in vaccinated people, and an estimated >20% of the infected never developing any symptoms suggests reliance on symptoms or vaccination status inadequate.

Study personnel are responsible for maintaining a record of completed pre-screening checklists for all study participants. Audits to ensure ongoing compliance may occur.

P.I.s may propose an alternative screening checklist in their Safety Plan (for example, if required by sponsor or facility).

Pre Screening Checklist for Research Participants by phone or other remote device prior to AND at the time of arrival – each individual participant.

In the last 30 days, have you had a positive COVID-19 test? Yes No Are you unvaccinated? Yes No

In the last 14 days, have you experienced sustained close contact (such as a household contact, ‘ohana, caregivers and care receivers) with a person with a positive COVID-19 test or a person who is currently a person under investigation for COVID-19 infection (i.e. the person has been or will be tested for COVID-19)? Yes No

In the last 14 days, have you had a fever (greater than 100.4° F), chills, cough, sore throat, fatigue, headache, or diarrhea? Yes No

In the last 14 days, have you had cold or flu like symptoms? Yes No

In the last 14 days, do you have concerns regarding other potential symptoms (such as loss of taste, loss of smell, eye redness or discharge, confusion, dizziness, unexplained muscle aches, loss of appetite) related to COVID-19? Yes No

Have you traveled recently, especially international travel to any of the [CDC Level 2 – 3 countries](#), or have you been in close proximity to a person who recently returned from international travel, especially from CDC Level 2 – 3 countries? Yes No

If all answers are No, then the participant is eligible for in-person study interaction.

If any answers are Yes, it is recommended the participant is rescheduled and / or additional safety measures are in place.

Safety Guidelines if Proposing to Return to In-Person Research During the SARS-CoV-2 (COVID-19) Pandemic

→ Please include the following detailed information in your Safety Plan on the **Safety Plan Form**.

- P.I.s who wish to return to in-person research must submit a Modification application with a Safety Plan Form.
- The Safety Plan Form covers all five phases, therefore requiring only one Modification Application and Safety Plan Form.

Steps to Minimize Personnel Density, Allow Distancing, and Reduce the Chance of Transmission

The Safety Plan must be specific to your research area or situation and include safety considerations for your participants, research team, and community. Consider the following as applicable to your study:

- Describe the areas or locations (size, configuration, shared or single space, etc.) where people may be present, such as the lab, project space, and areas with common equipment.
- Describe the number of people that will be in the indoor ventilated area/space at any one time, a description of anticipated work schedules, including staggering, alternate days, partial days or other adjustments, and how work schedules will minimize personnel density and provide for general distancing of 6 feet or more.
- Differentiate the space where participants will be and the space where researchers will work and how density will be safely managed in each (if the spaces are different.)
- Describe whether or not the proposed safety modifications will be relevant to other approved research occurring in the same physical location. A modification application must be submitted separately for each approved protocol.
- State if coordination with other teams or labs also using the space or area is required, and if so, clearly describe how you will coordinate access to minimize personnel density.
- Describe situations or conditions where individuals will need to be in close proximity to perform work, operate equipment, travel, etc., and what steps will be taken to minimize contact time and lessen transmission risk.
- Describe any barriers, partitions or other methods to physically separate people that will be used.
- Describe any special PPE requirements beyond required cloth face coverings that will be required. Adhere to UH vaccination, testing, social distancing, and face covering requirements.
- Describe any work that cannot be done while wearing PPE or a cloth face covering and steps that will be taken to minimize the potential for viral spread.
- Describe other area/location-specific steps or considerations if applicable.
- Describe safe consent and/or assent procedures, and recruitment plans.
- Include details for personal health monitoring of participants and research personnel prior to interaction and coming to work.

Safety Guidelines if Proposing to Return to In-Person Research During the SARS-CoV-2 (COVID-19) Pandemic

Remote Consent and Assent Considerations ([NCICIRB](#))

- May occur via conference call, telephone, telemedicine, video conferencing, or other remote method.
- Allows the potential participant and researcher to engage in the consent / assent process similar to the in-person consent / assent process.
- Since the participant must reference the consent / assent document during the conversation, the consent / assent form must be sent to the participant prior to engaging in the consent / assent process conversation (via email, mail, etc.). If mailing, mail two copies so that the participant will keep a copy for their records and send the final signed copy back to the researcher.
- To support participant comprehension, suggest reading the consent / assent form to the participant, use plain language, and images or pictures if relevant.
- Documenting consent / assent can occur via by e - signature, email/fax, or text or photo image or a combination of these methods.
- If the research is minimal risk to participants, a waiver of consent documentation can be requested in the application.
- NCI-sponsored research must include a witness to the consent process to ensure that the consent/assent process conversation is observed by someone who can hear both sides of the conversation. There are no restrictions regarding who can serve as a witness, and the witness is not required to be impartial. Documentation must include the witness' name and that they were present for the consent / assent process and could hear both sides of the conversation.
- Check with your study sponsor regarding remote consent and assent requirements.
- On the consent/assent form, the researcher must document how the consent was obtained (via telephone or videoconferencing, for example).
- No research activities related to the study can begin until the consent process is complete.

Remote Participant Recruitment Considerations

Remote recruitment methods can include email announcements, advertising on electronic bulletin boards, in e-publications, or posting on relevant online social media groups.

How Information Will Be Communicated from the UH Human Research Protection Program (HRPP) and IRB

The IRB and HRPP are committed to providing real-time updates to our research community as the SARS-CoV-2 (COVID-19) pandemic guidance changes. Complete information will be incorporated into the webpage as it is developed. In addition, the IRB will email substantive changes directly to Principal Investigators, i.e., those with an active human research protocol in eProtocol from the uhirb@hawaii.edu account.

Safety Guidelines if Proposing to Return to In-Person Research During the SARS-CoV-2 (COVID-19) Pandemic

Connecting with Other Researchers Conducting SARS-CoV-2 (COVID-19) Pandemic Research

There are online resources that centralize collaborative research efforts. Suggested resources include Elsevier's [COVID-19 Research Collaborations](#), the [COVID-19 Collaboration Platform](#), the Center for Leading Innovation and Collaboration (CLIC) [COVID-19 website](#), and ClinicalTrials.gov [COVID-19 Clinical Trials List](#).

Additionally, the John A. Burns School of Medicine (JABSOM) has created a [COVID-19 resources page](#).

Research Taking Place Outside of the United States

All research activities conducted outside of the United States must also follow the IRB guidelines. Additionally, there may be other place-based guidelines. Researchers are asked to check with local collaborators and/or researchers to identify and comply with any additional guidelines.

Ceded Research Considerations

Whether or not research is reviewed by an external IRB, the UH IRB and HRPP research restrictions and guidelines apply.

These safety guidelines must be communicated to all of the relying site investigators by the overall lead P.I. of the study. Relying site investigators must also ascertain if their institution has implemented more restrictive requirements. Relying site investigators need to comply with whatever requirements are most restrictive and communicate this to the lead P.I.

Single IRB studies ceded to another IRB: If oversight for a research project is ceded to an external IRB, the UH researcher should communicate UH's guidelines to the overall lead P.I. and the reviewing IRB.

Remote Research Technology Considerations

UH Information Technology Services offers [SARS-CoV-2 \(COVID-19\) resources](#).

Safety Guidelines if Proposing to Return to In-Person Research During the SARS-CoV-2 (COVID-19) Pandemic

Priority IRB Review for SARS-CoV-2 (COVID-19) Pandemic Research

The UH IRB will prioritize review and approval of SARS-CoV-2 (COVID-19) pandemic research or changes to existing research because of the pandemic.

Resources and Who to Contact

Many resources have been developed and continue to be updated regularly. Here are some web links to support the research community:

UH

[Human Studies Program \(IRB\)](#)

[COVID-19 Guidelines \(Interim\)](#)

[System COVID-19 Information Page](#)

[Mānoa Coronavirus \(COVID-19\) Page](#)

[Environmental Health and Safety](#)

[UH System Human Resources COVID-19 Information and Updates for Employees](#)

Hawai'i

[Department of Health](#)

[Department of Hawaiian Affairs \(OHA\) COVID-19 Resources](#)

National

[Public Responsibility in Medicine and Research \(PRIM&R\) and COVID-19 and coronavirus](#)

Federal

[Centers for Disease Control and Prevention](#)

[U.S. Food and Drug Administration \(FDA\) Guidance](#)

[National Institutes of Health \(NIH\) COVID-19 Research](#)

[Office on Human Research Protections \(OHRP\) Guidance on coronavirus](#)

UH Human Studies Program Main Office Phone: (808) 956-5007

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Mahalo nui loa to our researchers who responded to our survey in 2020 with questions and concerns. Your thoughtful contributions helped guide the content and creation of these guidelines. The page 1 table is based on Hawai'i's "[Roadmap to Recovery and Resilience](#)" and "[Reopening Strategy](#)." Mahalo nui loa to the UCLA Office of the Human Research Protection Program (OHRPP) for inspiration and support.