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

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<th>Impact Level</th>
<th>IRB requirements for in-person research</th>
<th>Daily startup requirements</th>
<th>Managing Safe Distancing</th>
<th>Personal Protective Equipment (PPE)</th>
<th>Disinfection</th>
<th>Screening of personnel</th>
<th>Travel</th>
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<tr>
<td>RED</td>
<td>Pause all in-person human research (unless essential - clinical). Convert to remote interaction if possible.</td>
<td>Clinical research only (essential) - Pre-screen personnel and participants in advance and at meeting.</td>
<td>Clinical research only (essential) limit in-person</td>
<td>Clinical research only (essential) - Face shields and gowns for personnel; face shields for participants.</td>
<td>Clinical research only (essential) - Prior and after each appointment.</td>
<td>Personnel and participants immediately before activity; phone screen 24 hours in advance.</td>
<td>None</td>
<td>Mandated whenever possible. Submit a modification application.</td>
</tr>
<tr>
<td>ORANGE</td>
<td>Remote interaction if possible. Limited in-person with Safety Plan submitted via Modification.</td>
<td>Approved in-person research: Pre-screen personnel and participants in advance and at presentation</td>
<td>Maintain six foot distancing when possible, or request exceptions in Safety Plan.</td>
<td>Face shields and / or masks for personnel and participants; gowns for personnel (biologic contacts only)</td>
<td>Prior and after each interaction. Waiting areas and common spaces hourly.</td>
<td>Personnel and participants immediately before activity.</td>
<td>Approved in-person research: To remote sites as needed for essential clinical purposes only.</td>
<td>Encouraged whenever possible</td>
</tr>
<tr>
<td>YELLOW</td>
<td>Remote interaction if possible. Expanded in-person with safety plan submitted via Modification.</td>
<td>Pre-screen personnel and participants in advance and at presentation</td>
<td>Maintain six foot distancing when possible, or request exceptions in Safety Plan.</td>
<td>Face shields and/or masks for personnel and participants; gowns for personnel (biologic contacts only)</td>
<td>Prior and after each appointment. Waiting areas and common spaces hourly.</td>
<td>Personnel and participants immediately before activity.</td>
<td>Approved in-person research: To remote sites as needed.</td>
<td>Encouraged whenever possible</td>
</tr>
<tr>
<td>GREEN</td>
<td>Remote interaction if possible. Submit a modification application with safety plan if in-person.</td>
<td>Screen personnel daily.</td>
<td>Maintain six foot distancing when possible, or request exceptions in Safety Plan.</td>
<td>Face shields and/or masks for personnel and participants recommended.</td>
<td>Prior and after each appointment. Waiting areas and common spaces hourly.</td>
<td>Self-monitor for symptoms</td>
<td>Approved in-person research</td>
<td>Encouraged whenever possible</td>
</tr>
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</table>

- Report Unanticipated Problems immediately by sending an email to uhirb@hawaii.edu. Mahalo!
Phase 1: Essential clinical only

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 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
Phase 2: Minimal additional on-site and in-person research allowed

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:

- In-person human research where risk can be mitigated, as demonstrated in the Safety Plan Form. Researchers are encouraged to submit a Modification Application with the Safety Plan Form to propose in-person research such as Observation research.
- Human research that can be conducted remotely.

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 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
Phase 3: Additional onsite research personnel allowed

During Phase 3, the same forms of in-person human research allowed in Phase 2 may continue, however, additional research personnel in non-participant facing roles are allowed to return on-site. Plans must be developed and implemented to ensure on-site research personnel does not exceed maximum allowable capacity or the maximum capacity where appropriate risk mitigation strategies can be implemented.

- 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 on-site 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 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
Phase 4: Near-post SARS-CoV-2 (COVID-19) pandemic research phase

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

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.
Phase 5: Post SARS-CoV-2 (COVID-19) pandemic research phase

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, there is no limit to the number of people in a space 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.
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 Safety Plan Form via New or Modification eProtocol application 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.

- 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 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 balance between ensuring access to in-person research with the potential for direct benefit to participants and ensuring the health and safety of all involved.
Safety Guidelines if Proposing to Return to In-Person Research During the SARS-CoV-2 (COVID-19) Pandemic

Navigate Content

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

- Participant Pre Screening Guidelines and Checklist
- Steps to Manage Safe 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
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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 of the virus and virus variants involves long or short 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, vaccine and booster efficacy reduction over time, and an estimated 20% - 70% of infected people never developing any symptoms suggests reliance on symptoms or vaccination status inadequate. Other effective protective measures should be maintained.

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

<table>
<thead>
<tr>
<th>Pre Screening Checklist for Research Participants by phone or other remote device prior to AND at the time of arrival – each individual participant.</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the last 30 days, have you had a positive COVID-19 test?  □ Yes  □ No  Are you unvaccinated?  □ Yes  □ No</td>
</tr>
<tr>
<td>In the last 14 days, have you experienced sustained close contact (such as a household contact, ʻohana, 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</td>
</tr>
<tr>
<td>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</td>
</tr>
<tr>
<td>In the last 14 days, have you had cold or flu like symptoms?  □ Yes  □ No</td>
</tr>
<tr>
<td>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</td>
</tr>
<tr>
<td>Have you traveled recently, especially international travel to any of the <a href="https://www.cdc.gov/coronavirus/2019-ncov/travel/international-travel.html">CDC Level 2 – 3 countries</a>, 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</td>
</tr>
<tr>
<td>If all answers are <strong>No</strong>, then the participant is eligible for in-person study interaction.</td>
</tr>
<tr>
<td>If any answers are <strong>Yes</strong>, it is recommended the participant is rescheduled and / or additional safety measures are in place.</td>
</tr>
</tbody>
</table>
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 Manage Safe 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 face coverings that will be required.
- Describe any work that cannot be done while wearing PPE or a 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.
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 the Center for Leading Innovation and Collaboration (CLIC) COVID-19 website, and ClinicalTrials.gov COVID-19 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 UH 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 must 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 the UH HRPP'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) Ampersand, 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
Email: uhirb@hawaii.edu

These Guidelines have been updated in accordance with current local, national, and international public health safety measures removed and in-place, and pandemic status. Mahalo nui loa to our researchers who responded to our 2020 survey. Your thoughtful contributions helped guide the content and creation of these guidelines. Mahalo nui loa to the UCLA Office of the Human Research Protection Program (OHRPP) for inspiration and support.