Impact Level Changed to ORANGE

November 2020 Announcement and Instructions

Aloha UH Researchers and Research Team Members,

We hope you and your ohana are continuing to be well and safe. Thank you for keeping your participants and research teams safe during this pandemic.

In our previous email, we let you know that the IRB, based upon the statistics provided by Hawai‘i government agencies, had determined the potential risk of contagion was high enough to move the research impact level to red. (see IRB impact level safety guidelines for more information)

Currently, the City and County of Honolulu holds the impact level to Tier 2, (our equivalent impact level Orange). Please see the following links for the City and County’s statistics and tier status: Statistics ; Tier Status

As we shared with you in previous communications, the IRB’s decision making will tend to be more conservative and lag behind when local restrictions are lifted in an effort to protect participants, research teams, and the community.

Starting on Thursday, November 12th, the IRB impact level for in-person research will move from RED to ORANGE.

What does this mean?

• If you have an IRB approved Safety Plan, you can move to impact level Orange for in-person research.
• If you do not have an approved Safety Plan and wish to conduct in-person research, submit a Safety Plan form via a Modification Application in eProtocol. Visit our web page for impact level safety guidelines and the Safety Plan form.
• If the research will take place in a location other than O‘ahu, please include that information in the Safety Plan form.
• The requirement for a Safety Plan applies to studies in which one of the UH IRBs provided initial review and approval. Studies in which the UH IRB ceded review to a non-UH IRB would first need to follow the lead IRB’s guidance and also take into account any performance site requirements (such as hospitals or clinics).
Have a plan in place for rapidly returning back to impact level Red should the need arise. The IRB will keep a close watch on COVID-19 infection and death rates. If rates increase and further safety restrictions are put in place, we will return to impact level Red, meaning that your project must revert back to limited contact only as approved by the UH IRB.

We truly appreciate your commitment to keeping participants, research teams, and our community protected from the virus during this unpredictable and difficult time. Please contact our office at UHIRB@hawaii.edu if you have questions or need assistance.

UH Human Studies Program
Office of Research Compliance

Human Studies Program Reponse to COVID-19

In response to the rapidly evolving situation with COVID-19, the University of Hawai‘i, Human Studies Program (HSP) is requiring all UH researchers to regularly review their active human research protocols to help ensure the ongoing protection of research participants during this challenging time.

In-person interaction with participants in human research projects now poses additional risk, both to study participants and researchers. Guideline documents for researchers who wish to resume human research involving in-person interaction with participants have been developed. These documents have been developed with your feedback, the guidance of the UH Institutional Review Boards (IRBs), the contributions of key research teams across the UH System, and inspiration from fellow institutions and IRBs nationally.

Researchers are asked to follow the (color-coded) COVID-19 Impact Level chart. Restrictions on in-person research change based on impact level. Please use the Impact Level Safety guidelines to plan your research protocol. All new research protocols involving in-person interaction, and all requests to re-open in-person interaction for already ongoing research will need to include a safety plan addressing COVID-19. This safety plan should include proposed responses for all five impact levels. You may submit the safety plan using the Safety Plan form. All requests for resuming in-person interaction for existing approved research should be submitted using the HSP modification form in eprotocol (or the paper form, if the project is pre-eprotocol). If submitting your application using eProtocol, attach the Safety Plan Form on the attachment page. If submitting for a pre-eprotorotocol application, submit the Safety Plan Form as an email attachment.
Impact Level Safety Guidelines
Safety Plan Form

The Human Studies Program Impact Level chart is based on the State of Hawai‘i Impact level guidance. Please note, however, as a policy and as an additional safety measure, the UH HSP status will be carefully delayed behind the state level status by at least two weeks for opening or releasing restrictions. Researchers are to use the Impact Level chart to determine which provisions of their safety plan they may implement. It is quite possible, the impact level may become less restrictive or more restrictive. Please be sure to monitor the HSP website regularly, even after your protocol has been approved, to stay abreast of current guidance. The Human Studies Program will also notify researchers by email when Impact Level status changes.

The HSP in coordination with the IRB will review each submitted application for studies requiring face-to-face interaction and may have additional requirements or modifications to the study to ensure participant and researcher safety. The IRB will consider both the risk involved with COVID-19 and any potential benefit to participants.

UH researchers interested in resuming in-person human research are required to receive IRB approval before doing so by:

New Applications

- Review the updated COVID-19 guidance on our website.
- Review the Impact Level Safety Guidelines found on the COVID-19 page of our website.
- Fill out a Safety Plan Form found on the COVID-19 page of our website.
- Submit the Safety Plan Form via a New Application in eProtocol.
- You may also wish to include the COVID-19 safety information sheet for participants. The link for this document is on the COVID-19 page of our website.

Existing Approved Applications

- Review the updated COVID-19 guidance on our website.
- Review the Impact Level Safety Guidelines found on the COVID-19 page of our website.
- Fill out a Safety Plan Form found on the COVID-19 page of our website.
- Submit the Safety Plan Form via a Modification Application either via eProtocol, or an email to uhirb@hawaii.edu with a modification form for pre-eProtocol applications.
- You may also wish to include the COVID-19 safety information sheet for participants. The link for this document is on the COVID-19 page of our website.

Please do not proceed with in-person research until you have received IRB approval. Mahalo.
Informed consent considerations

In appropriate situations, the consent process can be conducted over the phone or by using other technology. Use of audio recording to document informed consent may be acceptable. Unless your protocol specifically states that consent will be done in person or otherwise prohibits the change, you do not need to modify your protocol. Consider whether changes to the consent process, and/or conduct of the protocol could mitigate risk of exposure to COVID-19. In certain minimal risk situations, it may be appropriate to request a waiver of documentation of informed consent (no signature needed) and include a statement in the consent form that participation implies consent. Requesting a waiver of documentation of consent can be done on the consent form page of the eProtocol application. If the application is “pre-eProtocol”, a waiver of documentation of consent can be requested via email to uhirb@hawaii.edu. In order to make changes, such as implementing a verbal consent process, or revising the consent process and form, you must submit a Modification of your protocol (attach updated consent documents).

Study participants should be provided information on the efforts that UH and the research community are making to protect both participants and researchers. The COVID-19 safety information sheet may be attached as an addendum to consent form documentation, for study participants.

Protocol Violations

It is recognized that there may be unavoidable protocol violations due to COVID-19 illness or control measures. Protocol violations do not need to be reported to the IRB unless they impose an increase in the risk of harm to participants, adversely affect the integrity of the data, or affect a participants’ willingness to participate in the study (see SOP 108 for details). Report protocol violations through eProtocol or by email for “pre-eProtocol” studies.