

University of Hawaii, Human Studies Program: Response to COVID-19

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

Due to the growing severity of COVID-19, person-to-person interaction now poses additional risk, both to researchers and study participants, especially when working with certain high risk populations. Additional restrictions from government authorities may further impact research activities in the days and weeks to come.

Researchers **must review their active protocols involving any face-to-face interaction** and consider whether it is possible to either:

1. **Delay** face-to-face interactions with participants until after the COVID-19 crisis has abated *or*
2. **Remove** person-to-person interaction from the protocol *or*
3. **Minimize** face-to-face interaction as much as possible in instances where participant safety requires that the protocol continue.

IRB Requirements for each scenario:

1. Delay. In general, this is the most preferable option and should be exercised when possible. If a UH researcher decides to delay enrollment and study interaction until after public restrictions due to COVID-19 have ended, a Modification form **does not** need to be submitted to the IRB. The Principal Investigator (PI) should contact the HSP office if a study is student-led and will significantly impact graduation, thesis/dissertation status.

2. Remove. In instances where face-to-face interaction can be removed from the protocol and replaced with an online or remote format (for example, using technology to conduct interviews such as telephone, videoconferencing, online surveys, etc.), a **Modification form must be submitted** through eProtocol to the IRB for review and prior approval. This can be done by selecting the "Start Modification Request" in eProtocol, or submitting the "paper" modification form via email for "pre-eProtocol" projects. The HSP will make efforts to review Modifications for COVID-19 as quickly as possible (these will be prioritized over other requests).

3. Minimize. For clinical and other critical research that requires continued enrollment and interaction with participants (for example, clinical trials involving therapeutic measures) researchers should provide a compelling justification why in-person interactions need to occur or continue. Ensuring the safety of study participants is paramount.

If continued interaction with participants is necessary while COVID-19 public restrictions are in place, a **Report form must be submitted** through eProtocol to provide the justification for either continued enrollment and/or face-to-face interaction with enrolled participants. This can be done by selecting the "Start Report Form" feature in eProtocol, or submitting the paper modification form for "pre-eProtocol" projects. In the Report form, address the following contingency measures:

- **Consider assessing potential exposure to COVID-19 before interaction.** If there is a compelling justification to continue face-to-face interaction, screen potential participants for active symptoms of COVID-19. If you need to meet with a potential participant, first

email or call them to ask if there is potential exposure to COVID-19 or symptoms of illness before any study-related visits and face-to-face interactions. Avoid or delay interaction with potential participants with exposure or symptoms of COVID-19. Follow current public health recommendations and US Centers for Disease Control and Prevention guidelines. ***This screening procedure does not require prior IRB approval because this is not a research activity.***

- **Research Personnel Safety.** For each day of enrollment/interaction, ensure that study personnel who will interact with participants are symptom-free and have not had possible exposure to COVID-19. Follow UH Office of Human Resources guidance and FAQs related to COVID-19. Address the use of Personal Protective Equipment (PPE) for research activities as appropriate.
- **Monitoring.** When a study involves in-person study visits to conduct safety monitoring of subjects (for example, drug treatment studies may involve regular examinations, administration of study drugs, or laboratory tests) researchers should consider alternatives to in-person monitoring visits, when possible. For example, interviews could be conducted by phone or email. A modified or delayed schedule of monitoring may also be possible.

The HSP in coordination with the IRB will review each submitted **Report** for studies requiring continued 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.

Deadlines

For scenario #1 above (delaying interaction), there is no need to contact the UH HSP (IRB) office.

For scenario #2 where your study involves interaction and you have the ability to modify your protocol to switch to remote contact, your Modification must be approved **prior** to implementing any changes. Halt interaction until your Modification is approved.

For scenario #3 involving clinical trials and other critical research in which you are requesting continued interaction during the pandemic, submit the required **Report** described above **as soon as possible** but no later than **April 6, 2020**. Halt interaction until the Report is submitted and you have received a response unless continuation of the research activities addresses immediate health and safety needs (such as continuation of study drug administration).

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).

Protocol Violations

It is recognized that there may be unavoidable protocol deviations due to COVID-19 illness or control measures. Protocol deviations 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 deviations through eProtocol or by email for "pre-eProtocol" studies.

Principal Investigator responsibilities

UH Principal Investigators are responsible for assessing active protocols and following these additional guidelines as well as other UH guidelines (including your UH campus' Environmental Health & Safety Office) in order to minimize participant exposure to COVID-19 due to their participation in a human research protocol. Should it be determined that a researcher did not follow these additional IRB requirements, studies may be subject to a for-cause audit and/or submission of a corrective action plan.

HSP Office Temporary Changes

We expect HSP to remain operational even if there are UH campus closures. Most HSP personnel are currently working remotely. UH IRB meetings will be held via videoconferencing until further notice. The IRB meeting schedule posted on the HSP website will continue as scheduled.

- Any paper-based forms that are usually submitted by campus mail or in-person drop-off should be emailed to UHIRB@hawaii.edu.
- Highest priority for review is given to all inquiries, requests, and protocol modifications related to COVID-19
- The HSP Office is currently closed to walk-in visitors except by prior arrangement with an HSP staff member. Most meetings will be held via teleconference or videoconference rather than in person.

Questions?

For questions, researchers are encouraged to email UHIRB@hawaii.edu rather than calling the main telephone line at 808-956-5007. If we miss your call, voicemails left on the main line are automatically forwarded to HSP personnel immediately via email. Arrangements can be made via email to schedule conference calls when needed to answer any questions or address concerns.

Stay Informed

Because COVID-19 presents evolving challenges, check the UH [HSP website](#) on a regular basis for the latest updates on UH IRB guidance, as well as the [OVPRI COVID-19 website](#) for messages to the UH research community in general. The main [UH website for COVID-19](#) should also be reviewed as major UH announcements are made on this page.

See also [FDA Guidance](#) on Conduct of Clinical Trials of Medical Products during COVID-10 Pandemic.

Your diligence and leadership during these challenging times is appreciated.

Mahalo nui, and Mālama Pono