



HUA IRB News

COVID-19 Update

The following content is from the HUA IRB [website](#). Updates will be posted to this [webpage](#) when new information is received.

Questions about COVID-19 and your research?

As the ongoing Coronavirus Disease 2019 (COVID-19) outbreak continues to change rapidly, here are some FAQ's that the Harvard University research community may find helpful:

[I need to modify my existing IRB submission immediately because of the COVID-19 impact. What do I do?](#)

Should you need to modify an existing IRB submission immediately, please contact the HUA IRB main email at cuhs@harvard.edu. In the email, list the study number and the reason for the revision. Your email will be routed to the IRB Administrator that is assigned to your submission and will be reviewed as soon as possible.

[Should I continue to be in contact with study subjects?](#)

Although there are no current restrictions to interacting with study subjects, please keep the following in mind:

- Remind study staff and study subjects of simple measures to lower risk and prevent spread of viruses (not shaking hands, practicing social distancing,

etc). Ensure easy access to handwashing facilities, and make sure alcohol-based sanitizers are readily available.

- As much as possible, limit the size of groups.
- Follow any guidelines or instructions from the specific facility where study subject interaction would occur. As some research may occur in another state, with another institution, or under the direction of another IRB (as in a reliance agreement situation), this is especially important. Please also pay attention to the Harvard School that you are associated with as additional restrictions may be in place.
- Consider the participant population (e.g., are they considered “high risk” for COVID-19?) and the setting in which the interaction would occur.
- Know and understand restrictions and other considerations based on the COVID-19 status of the areas that study subjects may be traveling from.
- Develop possible alternatives to in-person study visits such as using remote technology to instead of meeting in person.

In some cases, researchers may be able to move face-to face contact to an online venue such as through Zoom or Skype however there may be other studies where the study procedures do not easily accommodate an online substitute. There may also be protocols where harm may occur to study subjects should visits be postponed.

We realize that the COVID-19 outbreak may cause hardship to research, however it is also important to weigh the possible harms to subjects, taking all issues into account.

[Is the IRB Office open?](#)

The IRB Office is currently open. All IRB staff have the availability to work remotely, so IRB operations will be only minimally impacted should things change. We have also moved all regularly scheduled outreach and trainings to virtual meetings as much as possible. Check the IRB website regularly for updates.

Where can I find up-to-date information about COVID-19 for the Harvard Community?

Harvard has created a dedicated website that provides updates and community messages, school and program information, travel policies and campus restrictions, and other advice and resources related to the COVID-19. The website may be found at: <https://www.harvard.edu/coronavirus>

What do I do if I need to submit a change to my research, report new information, or start new research and the IRB office is not in operation?

The human subject protection regulations state that new human subjects research may not start without IRB review and approval. The regulations also state that no changes in already approved research may be initiated without prior approval by the IRB. The only exception is when a change is necessary to eliminate apparent immediate hazards to study subjects. But even in this situation, you will still need to report the event to an IRB. So, what do you do if your IRB is not in operation?

Complete closure of the Harvard IRB's would be an extremely rare occurrence as all Harvard IRB offices use an electronic submission system, can work remotely, and can hold an IRB meeting virtually. However, if the Harvard IRB offices are not in operation, the Harvard IRB's (Harvard University Area and Harvard Longwood Area) will pool resources to ensure that IRB review will occur. As the Harvard IRB's have initiated the Harvard Master Reliance Agreement, researchers from any area of Harvard would be able to receive review from any Harvard IRB should this dire situation occur.

As the COVID-19 situation evolves, we will keep you updated on next steps as it relates to ensuring IRB review for all Harvard researchers.