

Human Subjects Research – COVID-19 Amendment FAQ

What kind of changes might I need to make as a result of the COVID-19 restrictions?

- Change in how you collect data – e.g. replacing face-to-face interactions with online or phone interviews, online surveys, video conferencing, mail in surveys etc.
- Change in the data you collect – e.g. will you now need to collect and store more personal data such as email addresses, postal addresses etc.
- Unscheduled pause in research – e.g. unable to access participants safely, research sites closed so unable to continue observations until reopened etc.
- Change in the length of time data collection will need to take place over – e.g. participants had originally consented to 6 months of collection, which now needs to be extended because of COVID-19 restrictions.
- Expand or amend research to investigate the impact of the COVID-19 restrictions
- Changes in how you compensate subjects – e.g. replacing physical gift cards with electronic ones

If making changes to your research to address COVID-19 restrictions will have any kind of negative impact on the quality of your research, then you may want to consider simply pausing the research until a time when the restrictions are lifted. If this is something you are considering, please check in with your advisor/committee and the Research Support Team to make sure this would not adversely impact your overall academic timeline, and that any sponsor funding requirements in order to pause are identified and adhered to.

How do I know if I need to make amendments to my protocol?

Simple answer – it depends!

The first place to start is the risk level your protocol was originally assigned – this information will be included on your original approval letter from the IRB, and will let you select the applicable guidance from the UA Human Subjects Protection Program (HSPP) to see if your proposed changes would need an amendment to be submitted for review.

For protocols initially deemed EXEMPT:

https://rgw.arizona.edu/sites/default/files/exempt_research_2019-01_clean_0.pdf

For protocols initially deemed MINIMAL RISK:

https://rgw.arizona.edu/sites/default/files/minimal_risk_research_2019-01-21_clean.pdf

For all other protocols:

https://rgw.arizona.edu/sites/default/files/amending_approved_research_revised_2019-07.pdf

If, after reading through the appropriate guidance for your protocol, you are still unsure as to whether you need to submit and amendment – please reach out and ask. Because each protocol is project-specific, it is not possible to have a single response, because the same small change could have a very different impact on risk depending on the nature of the project.

OK – I know I need to make an amendment, so how do I do it?

Firstly, you will need to complete an Amendment to Approved Research form, which you can find here:

https://rgw.arizona.edu/sites/default/files/amendment_approved_research_v2019-06.pdf

If you are making any changes to already approved documents, for example consent forms, surveys, instruments etc, please make them using tracked changes on the original approved versions, and save with the same file name, just update with the most recent revision date. These will need to be submitted for review along with the amendment form.



If you have not yet started your recruitment, or you still need to obtain consent from some participants, you will need to look at how you will collect and document this consent. For example, you may be moving to collecting data through an online survey tool such as Qualtrics, where participants would read the consent online at the start of the survey and check a box to show they consent rather than provide a wet signature. If this is the case, you would need to complete the Alterations/Waiver of Consent or PHI form and include with your amendment submission. This can be found here: https://rgw.arizona.edu/sites/default/files/appendix_waiver_v2019-08.pdf

In some cases, you may even want to add in new instruments, or even a new population to your research – especially if you are trying to incorporate the effect of COVID-19 restrictions into your research. If this is the case, you will need to include the new documents, consent forms as part of the amendment submission.

If this seems a little overwhelming, especially right now, please know that you can get support and assistance for this process from Anna Bounds in the Grants Management Team. Anna's job is to reduce the administrative burden on you, and she is happy to walk you through each stage. This includes completing an initial draft of the amendment forms and any additional documentation for you to review. She can be reached at annabounds@arizona.edu, on (520) 621-8436 or via Zoom. Be prepared to provide her with your original submission and the final approval email with approved documents attached as she will need this to make sure that she has all the necessary project specific information. Anna has also been designated as the central point of submission for all COVID-19 related IRB amendments for the College of Education, so once you are ready to submit the amendment, please email all necessary documents to her and she will coordinate the submission on your behalf.

Wait I have more questions....

Given how frequently things are changing, this is completely natural. To help with this, Anna is working with colleagues at the HSPP to compile an FAQ of COVID-19 IRB protocol related queries. Whilst these, as previously mentioned, may well end up being very project specific, it is hoped that this will be a good starting point when you are considering any changes to your current research.

If you have any questions, please ask Anna, and if she can't answer them straight away, she will work with colleagues at HSPP to get you a response as soon as possible. You can also contact the UA HSPP directly with questions at VPR-IRB@email.arizona.edu. If it's related to COVID-19, please label the email as such so they can prioritize appropriately and copy Anna in to the email.

If you have already contacted the HSPP with concerns or questions about your specific project and received a response, would you please forward this to Anna at annabounds@arizona.edu so she can add it to the central document so that we can all benefit from the guidance.

At this time, no face-to-face research can occur without an essential research waiver approval. Please see the Research, Innovation, and Impact (RII) webpage for more information about the waiver as well as information related to COVID-19 in general: <https://research.arizona.edu/covid19/announcements>