

PROCESS AND PROTOCOL FOR COVID-19 RELATED AMENDMENTS TO ACTIVE IRB PROTOCOLS – March 19th 2020

This process is based on current guidance provided by the UA HSPP, and will be revised as necessary based on updates posted on the Research specific COVID-19 website here:

<https://research.arizona.edu/covid19>

This will apply to all IRB protocols where you need to make a change to research plans in order to eliminate immediate hazards to research participants as a result of COVID-19. This includes, but not limited to:

- Decreasing the number of protocol-mandated in-person study visits to healthcare facilities
- Replacing protocol-mandated visits to healthcare facilities with home visits, telephone, Zoom, or telemedicine, etc.
- allowing blood draws at remote or commercial laboratories
- Shipping investigational products directly to research participants
- Canceling a study visit in general due to low research staff support

Therefore, if a sponsor or investigator needs to make a change to research plans in order to eliminate apparent immediate hazards to research participants, these changes can be made and then reported to the IRB within 5 days, as per UA IRB guidance. If a full revised protocol cannot be completed in that time, a document that describes the changes and explains how they will protect subjects can be submitted, along with copies of any new or revised subject-facing materials.

This process will be coordinated by Anna Bounds from the COE Grants Management Team, and she can be contacted directly with any questions at **(520) 621-8436** or **annabounds@arizona.edu**

The key elements of the process are as follows:

Cross-referencing where possible: Anna has compiled a list of all active IRB protocols at the College of Education. She will cross reference these to the results of the Research Mitigation questionnaires that have received from both Faculty and Grad students to identify those IRB protocols where there will be some changes necessary as a result of COVID-19.

Single Point of Contact: Anna will be responsible for submitting all COVID-19 related IRB amendments to the IRB on behalf of COE.

Pre-completed Amendment Doc: To reduce the burden on Investigators as much as possible:

- Anna will complete the IRB Amendment document on behalf of the PI's based on the information they have provided on the Research Mitigation survey, and
- Anna will conduct follow up calls as necessary to ensure all the relevant information and any revised documentation.

Confirmation from 'missed' IRB holders: Anna will also be contacting those Researchers with an open IRB protocol that has not addressed in either the graduate or Faculty surveys to confirm:

- If the research in question is still ongoing
- If there will be an impact/need to amend protocol as a result of COVID-19
- Follow up with those researchers who identify a need for amendments to pre-complete the documentation for the amendments as above.