

CRP Re-Entry to Research Meeting Questions
Thursday, June 18th

- 1. Can we contact/recruit participants in a different manner than what we said in the approved IRB proposal?**
 - A. Do we put it in our notes? Yes, create a Note to File and place it in the study binder
 - B. What about an IRB modification? Per Mariette Marsh, this does not need IRB approval.

- 2. Are we able to have study monitors onsite for close out visits?**

At this point, we are closed to low and medium risk studies; however, this depends on the uptick level of COVID 19 cases. Most sponsors are on travel restrictions as well.

- 3. Will the University of Arizona setup training for donning (on) and doffing (off) of personal protective equipment (PPE)?**

Yes, the course is now available in UAccess Learning. The official course name is “Research: Personal Protective Equipment Training-COVID-19 Specific” and the UAL course code is UA-1662-1.

- 4. Any considerations for vulnerable patients, like those undergoing cancer treatments?**

Doctors will aim to continue treatment wherever possible, but they might need to change the treatment or prioritize certain treatments over others. Talk to the investigator and subject about the effect of the coronavirus outbreak on their treatment plan as they know the health of the subjects and will try to work with you to find the best plan.

- 5. Are these patient facing forms (once edited with study specific info) necessary to be IRB approved?**

The posters are already approved by the Reentry Plan and do not need IRB approval.

- 6. Do the Restart Checklists need to be used for ongoing studies that received a waiver?**

Yes. ***The process for restarting research involving human subjects is under development for UAHS studies.*** This includes studies for Colleges of Medicine-Tucson, Medicine-Phoenix, Nursing, Public Health, and Pharmacy. Additional guidance will be provided as soon as it is available. ***We will keep you updated when this process has been finalized and human subject’s research may begin reopening.***

- 7. If we had a waiver to continue research for safety, can we continue those visits for safety? For example, we need to do an ultrasound next week to check a patient’s SAE at Banner campus.**

Yes. See “[Pre-Procedure Testing FAQs](#)” and the “UA Banner Resuming Research Activities” FAQ listed on the Coordinators Corner webpage (<https://cats.med.arizona.edu/content/covid-19-documents>). These documents review utilizing Banner services with a UA research study. Please contact your department’s assigned Banner Clinical Trial Senior Manager (CTSM) with questions. Their contact and department assignment information is on our website (<https://cats.med.arizona.edu/content/banner-umc>).

- 8. Can coordinators complete the Restarting Research Checklist, or is the PI responsible to submit?**

This process is under development for UAHS research studies involving human subjects. We will keep you updated as more information becomes available. The PI will be responsible for all information related to their research studies.

- 9. We use CATS and they have safety processes in place. How does my team complete this checklist? Do we base it on what CATS does?**

Every PI is required to submit individual trials and identify the risk. This process is under development. Please do not submit until you are notified.

10. Does this Restart Checklist need to be completed for each study individually or all studies conducted in the department clinic?

This process is under development for UAHS research studies involving human subjects. We will keep you updated as more information becomes available.

11. I submitted my Restarting Research Checklist to Research Innovation & Impact (RII) website last week but received the response that approval was being held since it involved human subjects and needed further guidance from Banner. All of our studies involve patients. Is there any update on when this might happen?

Banner's current concern is addressing the influx of COVID-19 cases. UAHS & Banner are monitoring the situation and will inform the UAHS research community when it is safe for research to resume within the hospitals. UAHS is working closely with Banner and will provide updates as they become available. ***The reentry process is under development for UAHS research studies involving human subjects. We will keep you updated as more information becomes available.***

12. Is there a tentative date for reentry?

Given the surge, everyone is still looking for us to proceed cautiously for any non-Covid clinical research study involving human subjects. Currently there is no tentative date for reentry. The UAHS Reentry Team is assessing COVID-19 to make the best decision for the safety of our staff and subjects based on COVID-19.

13. Are we all allowed to use cloth masks?

Please see Mitigation Strategy for level of risk to determine PPE. The Mitigation Strategy can be found on the Coordinator Corner Website or on the Research Restart Plan under Human Subjects at <https://research.arizona.edu/covid19/research-restart>.

14. Will the University of Arizona provide staff with PPE and N95 masks?

If your research requires the use of PPE and/or N95 masks that may be an allowable expense on the grant. If you are working on an industry sponsored research study, check with your study sponsor. Place your PPE orders through your building manager with Facilities Management at <https://www.fm.arizona.edu>. For N95 fit testing please contact Rose Jacob (rjacob1@arizona.edu) with The University of Arizona Occupational Health.

15. How or will staff be notified if another staff member is sick?

As of 23 June 2020, UA Facilities Management (FM) will announce an Environmental Alert for that area and will provide a deep clean. FM will notify Campus Health. Campus Health will work with Pima County Health Department to notify people that someone in the area tested positive. ***This plan is still under development and will be circulated upon finalization.***

16. Where can we get the participant and approved guests screening forms?

Please go to the Coordinator Corner website (<https://cats.med.arizona.edu/content/covid-19-documents>) and forms can be downloaded.

17. Why hasn't the IRB approved my study?

Please email the IRB at VPR-IRB@email.arizona.edu for a status update.