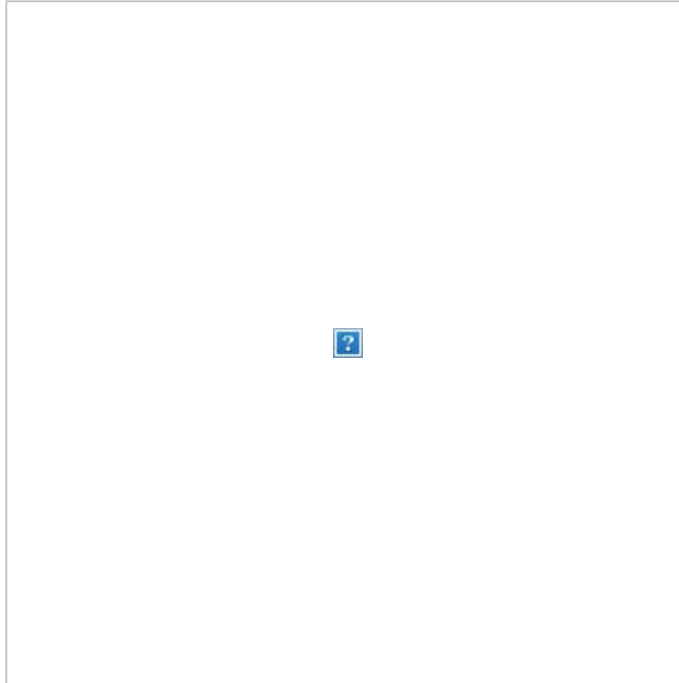


From: clinicalresearchcoordinators-request@list.arizona.edu
To: ["clinicalresearchcoordinators@list.arizona.edu"](mailto:clinicalresearchcoordinators@list.arizona.edu); ["uahs-oncore@list.arizona.edu"](mailto:uahs-oncore@list.arizona.edu)
Subject: [clinicalresearchcoordinators] Restart to Clinical Research -- A Message from the Vice Dean for Research
Date: Friday, August 7, 2020 2:59:36 PM

Cross-posting – Restart to Clinical Research for COM-T & COM-P

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August 7, 2020

Process to Restart Clinical Research

Dear COM-T Colleagues,

Earlier this summer, Arizona and Pima County experienced a surge in COVID-19. This appears to be regressing, albeit slowly. It is important that we continue to be vigilant, adhere to social distancing, wear masks/facial coverings and wash hands or use hand sanitizers. Below is a discussion on sensible steps to gradually re-start, on-site non-essential clinical research. Please carefully read through the topics, below. Many of these important considerations were discussed in the COM-T research town hall on July 22, 2020.

Principles: Research with human subjects must be conducted in a manner that focuses on the safety of our research subjects and study staff and decreases the risk of SARS-COV-2 transmission to the maximal extent possible as we resume a limited scale of clinical research under the phases of the UArizona Research Innovation & Impact's (RII) [Research Restart Plan](#). With input from COM-T, UAHS, and other UArizona colleges, RII developed Guiding Principles for Restarting Human Subjects Research (HSR) that were recently updated on July 29, 2020, and can be found [here](#) along with three additional

documents to prepare research subjects and study staff for research activities (a required Consent script, During your research visit flyer, and Participant Wellness Checks). These documents can be found on the Research Restart Plan website [here](#). PIs and study staff involved in human subjects research and those looking to start or resume non-essential research must review these documents and incorporate them into your research program. PIs should review these guidelines and — in conjunction with their department chairs and the entities where the research is to be conducted — develop a safety plan that reduces risk of SARS-COV-2 transmission. To minimize the risk of SARS-COV-2 spread, it may be necessary to pause certain aspects of research, and it is possible that some forms of resumed human subjects research may need to be curtailed in the future due to the impact of COVID-19 on our community. PIs should consider and plan for that possibility.

Considerations: It is critically important to remember that research with human subjects, or portions of that research that is being conducted remotely (e.g. virtually) should be continued in that manner. Likewise, studies or portions of studies that can shift in-person visits to virtual visits and other research activity that can be conducted virtually should be adapted as such. Consultation with the IRB may be needed. Additional mitigation measures are listed in the RII Guiding Principles document [here](#). These are the minimum required strategies for mitigating risk for each level, and should be adapted by the PI to their study after consultation with their department chair and director of the location where the research will take place. All research subjects and study staff must wear facial coverings or masks as described in the RII Guiding Principles Document. Mitigation strategies and standards set by the governing body of the location where the research is occurring takes precedence. Important considerations, among others, include limiting number of patient visits (potentially substituting remote data collection and consent processes), reducing the duration of in-person visits (optimally to less than 15 minutes), limiting the number of research subjects in a waiting room, pre-screening study participants and research personnel for symptoms consistent with COVID-19, instituting cleaning procedures, and utilizing personal protective equipment (PPE, face coverings and other measures). The University has also published new PPE training. The official course name is “Research: Personal Protective Equipment Training-COVID-19 Specific” and the course code is UA-1662-1. Please ensure that you and your staff have completed this training.

Checklists covering non-essential research that may be able to be approved for restart at this time: Non-essential research with human subjects in which the face-to-face research is carried out as part of an already scheduled on-site, clinically-indicated visit (e.g. not a visit strictly for research purposes) may be considered for restart. Invasive procedures must be clinically indicated, though exceptions for blood draws may be considered. Activities that can continue remotely (e.g. virtually) should continue in that manner, and activities that can be converted to a virtual interface should be conducted as such. A limited number of research personnel not already present may come on site for face-to-face, research-related activities if those activities cannot be accomplished remotely. There should be no coercion of any form. The safety of study personnel, staff and research subjects is the chief objective. Please be reminded that this should

constitute an incremental resumption of some research, carried out in a sensible manner, and not a return to pre-COVID-19 levels.

Specific research activities that remain on pause: Procedures conducted exclusively for research purposes that are aerosol generating (e.g. spirometry, bronchoscopy, intubation, etc) should not be performed at this time. Non-essential studies that require research-only, in-person visits by research subjects should not be re-started at this time. Exceptions for essential research can be considered on a case-by-case basis. These guidelines will be re-evaluated as we assess the prevalence of COVID-19 in our community.

Approval Process: Research that is and can be conducted remotely (e.g. virtually without a face-to-face visit) may continue in that manner, in addition to on-site research that is already covered under an approved research waiver. **However, every individual study will require submission of a research checklist.** Those with research waivers must still submit checklists and should indicate (in the Abstract/Brief Description section of the checklist) that a prior research waiver was obtained for that research and the rationale for the waiver at the time of issuance. COVID-19-related research will be assessed separately in the context of these waivers. Submitted human subjects checklists will be reviewed by the college associate or vice dean for research (or his or her designee) and if appropriate, the package will be forwarded to the unit where the research is to be carried out (e.g. Banner Health, CATS, etc).

- For research occurring in Banner Health facilities, once the college vice or associate dean of research reviews the checklist, it will be submitted to the Banner Clinical Trial Senior Manager, via the Research Intake Process email (researchapp@email.arizona.edu). Please be sure to provide the following information (in the Abstract/Brief Description Section) to help aid Banner in their review:
 1. What physical Banner space is being utilized for the study (this can be entered in Research Location Section) and will UArizona personnel be required to perform research-related procedures (entered in the Abstract/Brief Description Section)?
 2. Will the study require use of Banner personnel (nurses, staff, etc.)
 3. Does the study involve Banner ancillary services (medical imaging, etc.)
 4. Does the study involve invasive procedures that require pre-PCR testing prior to scheduling?

Once the unit has approved the checklist, it will be returned to the college for college-level approval and then on to RII for final review. Approval of a checklist will be signified to the PI in an email from RII stating that the “Reentry Checklist Result” is “Approved”.

Important procedures to follow regarding checklists: The Qualtrics Checklists were updated earlier this week to include: 1) a longer “Abstract/Brief Description of Research

Activities” and 2) a field to indicate the numerical level of research corresponding to the CV-19 Exposure Risk on the updated Guiding Principles for Restarting Human Subjects Research found [here](#). When filling out the Qualtrics Checklist, *please clearly and directly detail the nature of the research in the Abstract/Brief Description Section; important information to include: the potential for and nature of (duration frequency) in-person visits and procedures (if any) as well as the need for already present or new on-site research staff and mitigation efforts for both research subjects and staff.* Please also include the level of research here (and in response to the specific question later in the human subjects section) covered by the checklist that corresponds to the CV-19 Exposure Risk of the planned research. Please also include your email or the best way to contact you with questions on your research.

For those who have already submitted a human subjects checklist, you will be individually emailed an edit link to update your submission with the information requested in the above paragraph. Please note that once the link is clicked it becomes immediately deactivated and cannot be accessed again without requesting a new one. Please do not access the edit link until you are prepared to complete the update.

Please only submit a checklist or edit a checklist at this time for research that is either already under a waiver or qualifies for re-start as described above. Checklists and edits for checklists covering non-essential research that is not covered by the description above will be requested at a later date, once on-site research with human subjects is further expanded.

Closing remarks: As you are all well-aware, the COVID-19 situation is fluid and ever changing, and we want to carefully evaluate the restart of all clinical research studies to ensure that we can protect our research staff and participants, especially given the surge in cases we saw earlier in the State of Arizona.

Thank you for your careful work and patience as we restart research. Please contact me as needed with questions about your studies.

Sincerely,

Jason Wertheim, MD, PhD

Vice Dean, Research

Associate Professor, Departments of Surgery & Biomedical Engineering

