COM-T Research Town Hall

August 12, 2020

Zoom Recording: Link to Town Hall

The following are answers to questions posed at the Research Town Hall on August 12, 2020. Some answers have been lightly edited for clarity and updates have been provided.

1. **(Regarding checklists) If the PI has multiple research projects, how do we deal with answering questions about each?**

   If you have projects that are quite different, put in individual checklists for each. However, if you have two that are similar and you can distinguish them carefully, it can be put in one.
   A single checklist per study is the best guideline.
   **Update: Checklists covering studies with waivers can be grouped together into one checklist indicating that waivers have been obtained for the specific studies that are referenced.

2. **For checklists for studies previously approved under a waiver…**

   We have a study that everything done as part of it is purely for research. It involves 2 kidney injections, so patients have to come in for safety research visits. per the email the visits are okay to be done since it was previously approved by a waiver. however, MRIs, USs, renal scintigraphies also have to be done to assess safety. Are these covered by waiver or would have to be approved by checklist? I have written all of this in a checklist I submitted yesterday already. also is there a timeline for approval?

   **Update: If you have research that is covered under a waiver, those waivers can be converted to checklists. Specify in the checklist application that the research is covered under a waiver (if any part is not covered under a waiver, please state that and describe this research).

   For this specific example, the MRIs, ultrasound, and scintagraphies are done to assess safety, and that is done under the waiver. It should be able to be approved under the checklist.
   Right now, the timeline for approval is approximately 3 business days, sometimes quicker. If you have submitted a checklist and a week has past, please follow up with an email.

   - Dr. Wertheim jwertheim@email.arizona.edu
   - cc: Emily Nickerson: eknickerson@arizona.edu

3. **Hello! Thank you so very much! Can you please restate what kind of research is being considered to re-start?**

   This webinar was focused on research with human subjects; a face-to-face interaction with a research subject; clinical subjects coming onto the premises for a therapeutic or clinically indicated visit.
   **Update: For a specific description please see the August 8, 2020, archived email here.

4. **If we do not have waivers, can we still submit checklists?**

   For essential research:
   The University is trying to move from waivers to checklist as a matter of record keeping.
   If you already have a waiver, indicate that in the checklist, specify that you do have a waiver, and the indication it was for. It should be approved readily.
   For non-essential clinical research
   This webinar was discussing restarting non-essential clinical research, which is research not under a waiver and not restated yet. **Update: Yes, you may submit a checklist for non-essential research not covered under a waiver as described here.

5. **What if I did not receive an email with a link to edit my checklist?**

   If you have not received an email to edit your checklist, please email Dr. Wertheim and copy Emily Nickerson.
   jwertheim@email.arizona.edu, eknickerson@arizona.edu

6. **If a study uses the Research MRI 3T, may we submit the checklist now?**

   Yes, if your research only uses the MRI 3T you can submit your checklist now. If it is a larger study where you have research visits with Banner, that may be a bit more complicated. If so, please reach out to Dr. Wertheim individually.

7. **Are you reviewing/approving clinical research conducted at non-Banner clinics, or just Banner?**

   There may be some research occurring in facilities loosely related to the university. It would have to be looked at on a case by case basis. The checklist would be reviewed. The location would be contacted to verify that they could accommodate the research restart. It would be implicit that the other location must also permit the research to occur.

8. **The IRB is requesting checklists as part of submissions for new studies - research has not yet started and it is non-clinical research. Should we go ahead and submit the**

checklist to you now (even though active research activities will not be starting) so that we can provide the checklist to the IRB?

[Follow-up] The IRB is waiting for approval from the college first before approving an IRB study.

COM-T has been in contact with the IRB. The IRB is requesting checklists to give final approval from an IRB standpoint. The IRB will move forward continuing their review, but before the final approval letter is issued, they will need an approved checklist. Once your checklist is approved, they can give you your IRB letter of approval in a matter of hours.

Special Case: Waiting for funding to come in from a government entity or foundation, and the funding source is requesting an IRB approval letter. Let the IRB know, they can generate a specific letter that will allow those funds to be release.

9. **A patient visits Banner facility for a clinically indicated imaging exam. To screen for research eligibility, we need blood drawn, which cannot be performed at that imaging facility and the patient has to visit another Banner facility. (1) It is unclear if this additional visit for blood draw falls within the scope of the current phase; (2) If a research imaging exam involves contrast injection, is this considered an intervention? The imaging will occur concurrent with the clinically indicated visit. Thank you.**

   For this study, you are encouraged to submit a checklist. Be as descriptive of the research component as possible (is it the MRI or is it the contrast injection). Include locations of the procedures as well.

10. **When can undergraduate students participate in clinics for research or quality data collection?**

    This will need Banner consideration. Dr. Wertheim will follow-up with our Banner partners and include the follow-up.

    **Update: There are no broad restrictions on undergraduate research at Banner, however the work must be approved by the preceptor. There may be location-specific restrictions, such as the emergency department, some intensive care units and work with patients with known COVID-19 or with symptoms that may be due to COVD-19. Students, like all others, need to continuously wear a mask

while on site and follow local facility guidelines around single entry and exit points, ad screening.

11. **What is your expectation for timeline for allowing low risk human subjects research that is not clinically indicated?**

    Update: COM-T, UAHS and Banner are closely watching the prevalence of COVID-19 in our community. Next steps to either expand or contract clinical research will be dependent upon the extent of COVID-19 in the local region and considerations for the safety of study subjects and staff and are continuously reviewed.