Tip Sheet for Clinical Research Teams during COVID-19 Pandemic

Published April 9, 2020; Revised May 5, 2020

The below information is compiled to help guide and inform clinical research teams on ways you can optimize managing your clinical research projects and best mitigate the new challenges that we all are facing during the pandemic. Tips shared here are not meant to represent regulations or policies.

For full information related to research operations during COVID-19, be sure to regularly check the UNC Research webpage. For more information on UNC Health status and policies related to COVID-19, visit the UNC Health webpage.

If you have additional questions or tips you would like to share, please contact us at crso@med.unc.edu.

General Management and Oversight of Clinical Research Teams

1. Establish a plan for routine communication among team members. Be sure to define expectations for when team members will be available and the preferred method of communication about various topics (e.g. email for general updates, Zoom or WebEx for collaborative project development, text messaging for urgent questions, etc.). Reach out to your IT support personnel for guidance as needed.

2. Consider if adjustments need to be made to work plans. Do you and your team members have enough work to maintain the expected work hours? Is there work that is important, but had not previously been prioritized, that could be useful for the team to engage in now given fluctuations in normal job duties? For example, you may consider reviewing and updating or drafting new SOPs, developing new training materials, organizing electronic materials and files, performing data quality assurance reviews, completing remote training/developmental activities, developing new study proposals, etc.

3. Define a strategy for remotely monitoring general work progress. Without the ability to have quick, informal, in-person check-ins, it may require more focused effort to ensure everyone on the team receives enough timely and thorough feedback to continue to work successfully and efficiently. You may also want to consider establishing a more structured task/project management plan than you previously needed. Project management software, such as Microsoft Teams or Asana, may be beneficial in assigning tasks, setting due dates, and monitoring completion.

4. Consider establishing general communication times for your team members. This may be just quick chats or communications with no set agenda or even a virtual "water-cooler chat" session where your team can come together for camaraderie. Perhaps reach out to your team routinely to ask about personal wellbeing, new routines, challenges and innovative solutions!

Clinical Research Protocol Management and Operations

1. If your protocol requires ongoing in-person study visits that are allowed to continue per current UNC Research policy, consider clustering visits around limited days and times to minimize the amount of time your study team needs to be on campus. Also consider whether one study coordinator (who has received appropriate training and delegated authority) can manage the in-

person study activities for multiple study protocols, even if he/she is not typically the primary coordinator. If multiple staff must report to campus for essential activities, be sure to stagger those on-site work hours to promote social distancing. If your protocol requires very frequent visits, consider discussing with your sponsor potential options for minimizing the frequency of visits by combining activities to fewer individual visits and/or performing some activities remotely that are typically completed during essential in-person visits (with appropriate approval), such as reviewing medications or completing questionnaires.

Always be sure to check with your supervisor before reporting to campus to ensure you will be compliant with current policies and requirements (such as wellness screenings and mask usage).

2. Study personnel must screen participants for COVID symptoms 24 hours prior to an in-person research visit. Research personnel who have Epic access and the ability to create telephone encounters, can document COVID-19 screening for outpatient visits. You must be logged into Research Support or an outpatient department in order to access the Travel Screening questions. This Epic documentation notifies front desk staff that screening has been completed and alerts everyone of a possible COVID-19 infection. Please refer to the COVID-19 screening and documentation tip sheet for additional information.

3. If you are now conducting some study activities remotely (e.g. by phone, email, other virtual communication), remember that communicating without face-to-face interactions can be challenging. Communicate clearly and directly and be patient in receiving responses. Be sure to allow enough time and opportunity for participants to ask questions or share concerns. Whenever possible, schedule phone calls in advance and set clear expectations for length and frequency of contacts, as well as for receiving information back from the participant (e.g. in response to an email).

4. Be sure to talk with your sponsor about acceptable alternatives to traditional pen and paper signatures if applicable. This may include options such as Adobe or other electronic signature tools, or even email documentation. Be sure to document any changes, the reasons for the changes, and ensure the entire study team is appropriately informed.

5. Consider tools available to assist you in remote visits with research participants. Visit the UNC Safe Computing website for information and guidance on approved tools and services. Remember that virtual meetings in which protected health information (PHI) may be discussed must be conducted via an approved, secure method such as a Zoom HIPAA subaccount or SOM Webex. Consult with your unit's privacy liaison or the Institutional Privacy Office if you have questions.

6. Maintain vigilance in your responsibilities to uphold privacy and confidentiality. Make sure you have a private location in your home for phone conversations. Consider using a headset and avoid using speakerphone whenever possible. Be sure you are saving documents and materials according to the study plan in an approved, secure location. Be sure to lock your computer when you are not working on it and keep any paper files organized and maintained in a private location (not laid out in plain sight).

7. If you need to submit modifications to the IRB to instate changes in your study related to working during the pandemic, or are submitting a new COVID-19-related research project, be sure to include the word "COVID-19" in the submission cover page. This will prompt expedited routing for review by the IRB. As a reminder, initiating research or modifications to research without IRB review and approval is not permitted, except where necessary to eliminate apparent immediate hazards to the human subjects per DHHS OHRP and FDA regulations. For more information on IRB updates related to COVID-19, please visit the OHRE website.

8. If you will have remote monitoring visits during this time, be sure to review the new SOP for requesting research monitor access to Epic and complete the required forms. Note, there is an additional form specific to research monitor visits during travel restrictions. Details can be found on the UNC Research Central website and the HIM Sharepoint.

9. If your essential study activities include processing or managing bio-specimens, continue to follow standard precautions when handling clinical specimens, all of which may contain potentially infectious materials. Standard precautions include hand hygiene and the use of personal protective equipment, such as lab coats or gowns, gloves, and eye protection. Follow routine laboratory practices and procedures for decontamination of work surfaces and management of laboratory waste.

10. If you need to receive deliveries from vendors or sponsors that are essential for your remote work, ask that those supplies be delivered to your home address to eliminate any need to report to campus unnecessarily. Additionally, UNC Procurement Services has worked out an arrangement with CDW-G and Staples to provide equipment and supplies to home addresses. Reach out to your business manager for additional information.

Clinical Research Financial Management

1. Under current policy, research personnel who must report to campus for designated mandatory on-site study work will receive 1.5 times normal compensation for those hours required to be on-site. Compensation may be paid 1.5 times the normal hourly rate or compensatory time may be provided at 1.5 times the hours worked. Work with your team to develop a strategic plan to minimize required on-site time as much as possible (such as clustering visits and preparing in advance to increase efficiency while on site). You may consider allowing personnel who are required to report to campus for limited work to work fewer overall hours per week to keep personnel expenses within the normal budget (*typically employees must work at least 32 hours per week to maintain full-time status and benefits; be sure to discuss any potential changes with your HR representative*).

2. Consider having proactive discussions with study sponsors about potential impacts to your study budgets. Be direct about our circumstances and your efforts to appropriately manage the protocols. You may wish to inform your sponsor that we are required to pay 50% more wages to employees working on-site and either ask for additional funding to cover that expense or negotiate for more remote study activities (when feasible). If your payments are linked to completed monitoring visits,

request that payments will continue based on remote monitoring or other alternative milestone reporting.

3. If you previously received payments from sponsors via check, consider asking your sponsor to send direct deposit electronic payments. This would help minimize the need for onsite activities for personnel beyond your immediate research team. Be sure to document changes and ask your sponsor to notify you directly when payments are processed.

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