The SOM Clinical Research Support Office (CRSO) has compiled these general tips to help manage our clinical research work during these unprecedented times. Be sure to check out the initial tip sheet published on April 9th, available for review on the CRSO website.

If you have tips you would like to share with the UNC clinical research community, please contact us at crso@med.unc.edu.

Research Conduct Considerations:

1. If you are considering conducting clinical research activities on-campus, be sure to complete the Critical Activities Request Form – COVID-19 in advance and submit it via email to VCR@unc.edu. If you have multiple research projects to report, you may consider attaching a table with all of the required information for each study, rather than completing separate forms for each individual project.

2. When conducting study calls or visits from your home or other off-campus location, please be sure to deactivate any in-home smart technology (such as Alexa or Google Home), as these devices may inadvertently capture or record private information.

3. When planning to conduct study visits remotely, consider whether you have any IRB-approved study informational materials that you could send to your participant in advance to help facilitate the discussion. Remember, if you are altering your research processes, be sure to submit those changes in advance for IRB review and approval (include "COVID-19" in the coversheet).

4. If you are considering conducting research activities at or with any of the network entity hospitals (with appropriate approvals given the temporary COVID restrictions), be sure to reach out to the UNC Health Office of Research Support & Compliance (ORSC) as early as possible in the process to discuss feasibility, logistics, and resources related to your proposed research activities. Investigators should complete the brief collaboration survey to initiate that discussion. For more information about the ORSC or research in the UNC Health network entities, contact ORSC@unchealth.unc.edu.

5. If you are planning or initiating a multi-site clinical research study, the Trial Innovation Network may be able to provide resources to assist you in that work. Available resources include data coordination center support, single IRB services, standardized contracting, recruitment planning, and feasibility consultations. If you would like to learn more or submit an application for resources, please request a consultation from NC TraCS.

6. Remember, if you have made changes to a clinical trial protocol that have been or will be communicated to study participants or changed your recruitment status (such as pausing recruitment), be sure to update your protocol listing on clinicaltrials.gov.

Research Data Considerations:

7. If you are modifying your methods of data collection, such as moving from in-person interviews to remote interviews or self-report questionnaires, be sure to consider the ongoing validity of

the data. There may be alternate instructions or guidance based on the revised collection methods to maintain data validity. Also, be sure to note exactly when and how changes occurred so that can be referenced when you are conducting data analyses in the future. If you are unsure how changes may affect the validity of your data, consider reaching out to your biostatistician for further discussion.

8. If your clinical research activities include developing or maintaining registries, check out the NC TraCS Research Registry Toolkit. The toolkit includes registry-relevant content about recruitment and engagement, data, and regulatory topics, and focuses solely on registries used for research purposes.

General Considerations:

9. If you have additional time available, consider completing educational development activities or working on tasks that will bolster your research team's efficiency, compliance, and/or preparedness once typical workloads resume.