

Clinical Trial Considerations – COVID-19 (3/23/2020)

Which trials should suspend enrollment?

- Evaluate whether trials that require face-to-face contact between patients and research staff/providers are wise
- Consider suspending enrollment to trials that do not offer clear clinical benefit (e.g. phase I dose-finding or safety trials and phase III trials where a non-experimental equivalent is available)
 - o Phase II trials that are already underway and show potential for clinical benefit can continue enrollment but need to exercise judgment
 - o Possible exceptions for phase I and III trials include: a) the patient has been waiting for a slot that has opened up; b) the use of resources on the trial would be less than standard clinic care and the risk of ICU care or hospitalization is low
- Consider the following, among others:
 - o Benefits of enrollment
 - o Risks, including need for additional clinical visits, potential hospitalization, more limited safety monitoring
 - o Clinic and study team resources available
 - o Lab staff availability to process clinical and research samples; social distancing rules may reduce the number of staff present
 - o Non-critical testing in certain departments, e.g. pulmonary function labs, may become unavailable

How do I minimize exposure to research staff?

- Designate the minimum number of research staff to cover research needs; e.g. minimize potential exposures
- Consider the suspension of sample collection for ancillary studies; these collections may result in unnecessary exposure for both staff and patients
- If you need someone in the office at all times, consider having a back-up person(s) delegated to work remotely and rotate this between your staff regularly in case someone gets sick

How else can we minimize patient exposure/patient risk?

- Explore the option of telehealth visits for patients and the possibility of conducting procedures at local doctor's offices – blood draws, EKGs, assessments, etc.
 - o Ensure that any study-related procedures that are performed locally are billed to the study; send local office a memo regarding this
- Look into shipping oral medication to study patients so they do not have to travel to pick it up
- Review your IRB policies concerning emergency protocol modifications
 - o For example, some cancer center IRBs will accept retroactive research modifications documenting study procedures that were changed to minimize patient risk to COVID-19
- For patients on observational/sample collection studies who are already enrolled and continuing treatment, avoid bringing them into clinic solely for study visits

How to handle trials that have suspended enrollment?

- You may not need to officially suspend enrollment with your IRB; avoids extra paperwork
- If you are suspending on an investigator-initiated trial where you hold the IND, you need to inform the FDA
- You need to inform your Sponsor of enrollment suspension

How do I handle monitoring visits?

- Attempt to transition all monitoring visits to a remote capacity
- If appropriate, ask clinical research leadership at your center to draft an institutional memo supporting your requests for remote monitoring
- Check with your HIM department about provisioning remote EMR access to monitors