

University of South Alabama Health Guidance for Clinical Trial Research & COVID-19

The COVID-19 pandemic continues to evolve and impact increasing numbers of areas. This Guidance document provides general requirements and considerations with respect to patients enrolled, or being considered for enrollment, on USA Clinical Trials.

The University of South Alabama recognizes many of the challenges faced by our investigators who are charged with caring for our patients along with overseeing the clinical research in which their patients may be participating. These challenges may range from the ability of patients and families to adhere to protocol required procedures/timelines to the availability of investigators and study staff to manage the work associated with research. Important points to keep in mind:

- **Outside Visitors:** In accordance to prior USA Health directive, all outside representatives, medical science liaisons, and / or sponsor activity will be restricted and not allowed onto USA Health sites until further notice. This includes site-initiation visits, external audits, and / or chart reviews of patients on trials. Any activity that utilizes audio / visual or remote viewing will be allowed if feasible.
- **Communication:** Communicate any impact on their participation to currently enrolled subject(s) visits and/or treatment and contact patients to communicate any service interruption. Explain delayed or missed treatment to the patient and plan for future treatments as indicated by trial sponsor. Provide enrolled patients with 24-hour contact information for questions or issues.
- **New Studies:** New studies will not be opened for accrual of patients at this time. However, regulatory processes and budget development and contract negotiation may continue unless work force restrictions prevent this from happening.
- **Enrolling New Patients on Existing Studies:** A patient may be enrolled on existing studies during this time. However, prior to enrolling a patient on study, consider whether the key requirements, especially related to mandatory bio-specimen submission, will be feasible in your current work environment and feasible for the patient to be compliant. Investigators must use their best judgment in making determinations of protocol requirements in the context of challenges/risks posed by COVID-19.
- **Patients Actively on Studies:** For patients currently enrolled on a study, patient safety is paramount. Investigators must use their best judgment in making determinations of protocol requirements in the context of challenges/risks posed by COVID-19. Should a deviation from the protocol be required, it will be important to document the deviation, (documentation should be signed and dated) and include a notation that the deviation was related to circumstances surrounding the COVID-19 pandemic. All regulatory and sponsor notification and approvals remain in effect (see below). We anticipate that deviations related to the COVID-19 pandemic will be considered separately from other deviations at the time of a future audit.

- **Regulatory Activity:** Changes or protocol amendments for IRB approved ongoing studies must be submitted to the IRB. Normally, changes may not be implemented prior to IRB review/approval. Exceptions will be made when changes/amendments are necessary to eliminate apparent immediate hazards to the subject. If this happens, the changes MUST BE SUBMITTED to the IRB as a protocol deviation with 5 days. (See IRB Review and Researcher Guidance COVID-19 Document published 3.12.2020). Please note that all changes/amendments must be approved by the research sponsor prior to implementation.
- **Special Situations:** There is a rising concern with the use of immunotherapy (or agents that might impact the immune system) and the potential for it to exacerbate or negatively impact the immune response in patients who contract COVID-19. Currently, no agency has restricted the use of these agents, but we believe issues should at least be discussed with enrolled patients regarding continued use of immunotherapy. If alternative and equally effective treatments are available, we recommend choosing the alternative treatment at this time. USA Clinical Trials Office will continue to monitor these situations and plan on notifying any changes in recommendations as soon as possible.
- **Future:** USA Clinical Trials Office will continuously monitor this situation, with attention to recommendations from NCI-CTEP and other national organizations, in order to provide additional guidance for patients enrolled on USA Clinical Trial protocols.
- **Contact:** If any questions or concerns regarding this situation, please contact:

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We thank you in advance for your ongoing commitment to our patients, their families and our shared research mission at USA Health Clinical Trials. As more information emerges about COVID-19 and potential impact on our patients, we will communicate with you as expeditiously as possible.