University of South Alabama Health
Guidance for Clinical Trial Research & COVID-19
Revised June 8, 2020

USA Health continues to do its part in slowing the spread of the coronavirus pandemic. We are making clinical adjustments to adapt to new ways of functioning in order to reinstateclinical trial operations. This Guidance document provides general requirements and considerations with respect to patients enrolled, or being considered for enrollment and the management of USA Health Clinical Trials.

The University of South Alabama (USA) recognizes there are continued 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:

- **Staff Safety:** In accordance to current USA Health directive, all staff who enter any USA facility for work or other purpose will continue to be screened and cleared for entry. Screening includes temperature check and symptom questionnaire. Employees will wear a mask at all times; and other personal protective equipment as needed. Social distancing will be practiced when feasible.

- **Patient Safety:** In accordance to current USA Health directive, all patients and visitors who enter any USA facility for a clinic visit will be screened and cleared for entry. At a minimum screening includes temperature check and symptom questionnaire at each visit. All patients will wear a mask during clinic visits. Social distancing will be practiced when feasible.
  When feasible and ***at the discretion of the trial sponsor***, clinical trial related in person visits that do not require treatment, labs, physical exams and/or procedures may be performed by virtual telehealth visit.
  Currently, all adult patients starting a new chemotherapy regimen are being tested for COVID-19 prior to therapy. All children starting a new chemotherapy regimen who are symptomatic for COVID-19 are being tested prior to therapy. All patients with planned surgical or invasive procedure(s) requiring anesthesia are being tested prior to surgery/procedure. Accordingly, all clinical trial patients will be tested as well.
  When feasible and with prior approval from the IRB of record, e-consents through USA's RedCap database maybe considered to reduce the number of on-site patient visits.

- **Outside Visitors:** All activities that can be performed remotely using audio/visual technology will be performed as such, including site-initiation visits, external audits, and / or chart reviews of patients on trials. However, if deemed necessary for clinical trial participation, ***outside visitors/vendors who assist a clinical trial patient and surgeon/coordinator to the O.R. or other treatment area for the purposes of a clinical trial will be permitted after he/she are cleared through same screening process for***

employees. If those visitors do not pass the screening process, they will not be granted entry into the building and referred for coronavirus testing as indicated.

Communication: Any COVID-19 related impact on subject enrollment, subject visits, subject treatment or service interruption will be communicated to thetrial sponsor. Response to impact will be determined on a case by case basis as directed by the trial sponsor.

- **New Studies:** USA Health will resume the opening of new trials for accrual of patients. However, consideration will be given to feasibility to enroll based on patient volume, the ability to garner resources necessary, including personnel, to safely and effectively carry out the trial(s) proposed. New trial openings will be considered on a case by case basis.

- **COVID-19 Trials:** COVID-19 investigator, federal and industry initiated trials may be opened. This remains in effect until further notice. However, consideration must be given to the ability to garner resources necessary, including personnel, to safely and effectively carry out the trial. The IRB should be notified as soon as possible so that an IRB review can be initiated quickly. IRB will share the documents with the USA Health Clinical Trials Office that will review concurrently.

- **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 deviationDocumentation 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 SUMBITTED 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. The USA Health Clinical Trials Office will continue to monitor these situations and plan on notifying any changes in recommendations as soon as possible.

- **Future:** The USA Health Clinical Trials Office will continuously monitor this situation, with attention to recommendations from Food and Drug Administration and/or other national organizations, in order to provide additional guidance for patients enrolled on USA Health Clinical Trial protocols.

- **University Research:** All clinical trials will comply with the guidance provided in the University Research and Scholarship Ramp-Up Plan including principles and appropriate processes and requirements. Link to University Research and Scholarship Ramp-Up Plan

- **Contact:** If any questions or concerns regarding this situation, please contact:

Rodney Rocconi, MD
Elsie Colle Chair of Oncology Research
Associate Director of Clinical Research
Professor, Gynecologic Oncology
251-445-9812
rocconi@health.southalabama.edu

Winona (Wendy) Blount, RN, MSN
Director, USA Health Clinical Trials
(251)445-9834 office | (251)455-4566 cell
wlblount@health.southalabama.edu

Dusty Layton, MPA, BS
Executive Director
Office of Research Compliance and Assurance
(251) 460-6625
dlayton@southalabama.edu

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.