ALLIANCE
FOUNDATION TRIALS, LLC

Notification Updated to Include Remote Re-consenting of Study Participants

April 22, 2020

Alliance Foundation Trials COVID-19 Mitigation and Response Plan - *Updated April 22, 2020*

Dear AFT Investigators,

Alliance Foundation Trials has received frequent updates in the last few days from our sites and global partners about local and institutional restrictions on clinical trial activity in response to COVID-19. We appreciate the consistent flow of communication and hope this can continue until restrictions on the execution and oversight of our clinical research projects have been lifted. In response to the updates we have received to date, AFT will permit, effective immediately, the following steps to be taken by participating study sites and partner groups to sustain clinical trial activity in the face of rapidly evolving restrictions on clinical trial activity.

Institutional Review Board (IRB) Notification

As the study sponsor, AFT is allowing the following changes on all active AFT sponsored trials. However, any changes to policy or process at your site that impact patient treatment or overall data integrity should be submitted to your IRB prior to implementation. If your IRB approved policy changes are captured within the points defined in this memo, AFT will approve their immediate implementation. If your IRB requests broader changes to process at your site, please submit these changes to the AFT quality mailbox (quality@alliancefoundationtrials.org) for immediate review.

Remote Re-consenting of Study Participants (added April 22, 2020)

AFT has developed a guidance document for sites that do not have a policy in place for remote re-consent of study participants. Please note that remote consenting of new participants must be approved by the study Sponsor, AFT. Please submit these requests to your study specific Project Manager. The AFT guidance document can be accessed by following **this link.**

Remote Monitoring Visits

Many sites have already notified AFT of restrictions to on site monitoring. If your site cannot accommodate on -site monitors, please make every effort to permit access to relevant documents and patient charts to your monitors remotely in the place of schedule on-site visits. Some study CRFs are built to accept source document upload to key forms, these documents should be fully redacted before being added into Rave. Where this is not available, please contact your monitor to assess capability for the monitor to remote view your EMR, or to receive secure document transfers of properly redacted medical records for the purpose of source data verification. Please inform your AFT Project Manager (access the list by following **this link**) of any additional costs related to remote monitoring activity at your site as soon as possible.

If your site does not have an imminent monitoring visit, this might not be applicable, however consistent communication with your monitor and AFT about your capacity to host these visits will be crucial until your site's COVID-19 policies are withdrawn.

Remote Patient Visits

Any patient visits described in our study protocols that do not require patients to be in clinic for study assessments may be carried out remotely via telephone or telemedicine app. Visits defined in the protocol solely for the collection of patient health information such as adverse/serious adverse events, concomitant medications and disease recurrence/progression can be immediately transitioned to telephone contact. If a patient requires some additional assessments that require an on-site visit, all efforts should be made to conduct these visits per the protocol schedule of assessments. Please follow these links to access the **Site Impact Survey** and **Patient Visit Log** that should be updated and submitted to AFT frequently during the time that patient visits are restricted.

Use of Local Laboratories and Medical Centers for Standard Assessments

With the aim of reducing the number of visits that cannot be conducted due to patient visit restrictions at our sites, we will allow patients on all protocols to go to their local or primary care provider to have standard hematology or chemistry labs drawn, as well as physical examinations where possible, provided the records of these tests can be sent to the enrolling treatment site in a timely manner.

The use of local facilities (when feasible) to confirm patients meet safety requirements to begin new cycles of treatment per our protocols can be combined with remote follow up for data collection to complete a patient visit according to protocol. Investigators must have the ability to continue to review and sign off on test results in a timely manner. We hope that this additional flexibility will allow our sites to keep patients on treatment and on the protocol during the period of disruption to normal practice due to COVID-19.

Shipment of Study Drug and Questionnaires

If your site has a defined policy for shipment of study drug to patients through the mail or by courier service, this policy must be shared with AFT prior to implementation on AFT protocols. Once these policies have been reviewed, AFT will confirm with sites if shipment of study drug to patients is acceptable on a given protocol. If your site is interested in implementing this process, please send your policy to your specific Study PM as soon as possible.

Additionally, AFT will permit all sites to distribute study specific patient paper questionnaires to patients via mail or, where applicable, email. Patients must provide approval, per your institutions' policy, if emailing forms. If patient signatures or initials are required on these forms, please provide return shipment materials to the patient to help improve adherence to protocol collection time-points.

We recognize that shipment of materials to patients will come at a financial cost to our sites. Please send invoices that include the specific study number, indicating that this is related to COVID-19 to AFT at ap_invoice@alliancefoundationtrials.org. This is only for any additional costs related to material shipment to AFT. We will cover reasonable costs related to this activity until COVID-19 policies are rescinded at your sites.

Documentation of Protocol Deviations for Study Assessments Missed Due to Patient Visit Restrictions

Given the uncertain duration of restrictions on activity at AFT trials sites, we would like sites to plan for collections of all data required to retain patients on trial and answer the core scientific questions of our study protocols. If there are any assessments that cannot be conducted due to limited patient availability in clinic, please ensure that these are documented as protocol deviations. There may be cases where some assessments can be completed at a later date, notably for correlative lab draws with wide visit windows, and we want to be aware of the scope of missed assessments even if some core data collection is still possible at protocol defined patient visits.

The COVID-19 response has evolved quickly in recent days and we anticipate that further changes will likely require revision to this document. AFT will promptly notify all sites if this process is amended or retracted as more information becomes available.

Thank you all for your dedication to our patients and to the research that strives to improve their lives. We have already seen how effective communication, creative problem-solving, and attention to detail on the part of Alliance researchers is helping all of us to weather this storm.

Sincerely,

President

Chief Operating Officer