Evolution Research Group Risk Mitigation Response Plan COVID-19

Site: Woodland International Research Group (WIRG), Little Rock, Arkansas
Version Date: 21APR2020

Purpose:

This response plan's purpose is to provide structure surrounding the management and contingency plans during the COVID-19 pandemic or other crisis as determined by Corporate Management at Evolution Research Group (ERG).

This response plan is applicable to all staff at the Site location noted in the header of this document. It is the responsibility of the Site Director at the location to ensure proper execution of this plan.

This plan will be reviewed and further amended on a routine basis as information is learned or provided as applicable from the World Health Organization (WHO), the Center for Disease Control (CDC), the Food and Drug Administration (FDA) and other regulatory bodies as applicable to ensure consistency with expectations, rules and guidelines. As the plan content is amended it will be pushed to the ERG portfolio sites to be promptly populated with their site-specific information.

Plan:

A. General Volunteer/Subject Management

a. Volunteers should be contacted by phone prior to arriving at the facility to ensure they are asymptomatic. When calling our subjects/ caregivers to remind them of their appointments, ask whether they are suffering from respiratory symptoms such as a cough, fever, or shortness of breath. If so, they should be rescheduled once they are feeling better. These questions should be included in a prescreening/screening evaluation and the potential subject rescheduled once they are symptom free and approved to come in by a PI/Sub-I or Medical Director. The volunteer should then be instructed to contact their Primary Care Provider (PCP) and the sponsor should be notified, where applicable of the out of window visit due to this reason.

i. Note: Only Caregivers will be permitted to attend visits with subjects, if required per protocol. Subjects will be reminded that any guests that accompany them will be requested to remain outside of the clinic.

b. If a volunteer requires transportation to the clinic, the driver will make every effort to only pick up one volunteer at a time and disinfect in between rides. If additional subjects require pick up, the subjects must be alerted prior to arrival to ensure they are comfortable. Masks and gloves will be made available to those that require it prior to getting into the vehicle. The driver will take temperatures prior to entering the vehicle and documenting this.

    i. Note: If a driving service is utilized, the subject will be instructed to not get into the vehicle and come to the site if they do not feel well.

c. Once volunteers arrive at the clinic, they will be required to have a temperature check upon entering the facility (unless they were checked upon pick up from site transport), they will be asked to sanitize their hands and they will be required to complete a health questionnaire.

d. Volunteers will only be taken to areas where they are required to be seen and don the necessary gloves or face masks as available or as instructed.

e. Rooms that volunteers/study participants may be seen in must have all unnecessary items removed prior to entry and only the required equipment available (i.e. not the whole lab cart, iPads should be removed from their cases so they can be cleaned, designated BP cuffs should be used and the source chart should be kept outside of the designated room). Immediately after a volunteer is removed from a certain area, the room must be disinfected.

f. Any deviations to any required study procedures must be documented, *in detail*, and rationale outlined as it relates to the pandemic.

B. Inpatient Visit Management

a. The subject census will be reduced to a size that can be appropriately managed to protect the safety of the staff and other subjects.

b. Upon arrival at the site, the subject will check-in in the lobby, at that time the subject's temperature will be taken, the subject will sanitize their hands and the

subject will be required to complete a screening questionnaire. If the subject is cleared to proceed further through the clinic, the subject will be escorted to the inpatient unit, at which time the subject will be assigned a private room that has been sanitized.

c. Once the subject is in their room and a search of their belongings has been conducted, the subject will then proceed with screening activities.

d. Prior to initiation of screening procedures, the room in which informed consent will be obtained will be sanitized. The informed consent process will be followed, and the subject will either keep the pen which they are using, or the subject will be required to dispose of the pen themselves.

e. All equipment that is used for each subject will be wiped down upon completion of procedures or assessments. Items such as tourniquets or writing pens (for subject completed assessments) will be disposed or assigned to the subject during their stay and disposed upon discharge. Study equipment, such as but not limited to, pulse-oximeter, blood pressure equipment, IV pole, wires from ECG, clipboards, etc. will be disinfected prior to and after each use. Each room in which assessments/procedures are completed will be sprayed with disinfectant spray upon completion of assessments/procedures.

C. Outpatient Visit Management

a. If a subject is from out of state, the study coordinator will request permission in writing from the sponsor/CRO to complete a remote visit. If IP dispensing is required, site will request for site staff to deliver IP to the subjects in the event that the state boarder is not closed. If virtual visits or delivery of study drug is not approved by the Sponsor, the subject will be terminated from the study. Documentation of decisions made, and approvals will be available in the subject's source.

i. Note: Every effort will be made to retain the subject, specifically if it is in their best interest and well being to remain on IP. Otherwise, the discussion will continue with potential termination steps.

b. Upon arrival at the site, the subject will check-in in the lobby, at that time the subject's temperature will be taken, the subject will sanitize their hands and the subject will be required to complete a screening questionnaire. If the subject is cleared to proceed further through the clinic subject will be escorted to the appropriate area for study procedures to take place.

c. Prior to initiation of screening procedures, the room in which informed consent will be obtained will be sanitized. The informed consent process will be followed, and the subject will either keep the pen which they are using or the subject will be required to dispose of the pen themselves.

d. Subjects who are presenting to the clinic for routine study visits will be escorted through the clinic by the study coordinator conducting the visit to ensure that all assessments are completed as required per protocol. Upon completion of all visit procedures/assessments, the subject will be placed back into the lobby so that the coordinator can wrap up the study visit and dispense IP if required. Site is scheduling subjects so that there will be minimal subjects in the lobby simultaneously.

e. Staff traffic in and out of procedure/assessment areas will be limited. Staff members assigned to each subject will be limited

f. All equipment that is used for each subject will be wiped down upon completion of procedures or assessments. Items such as tourniquets or writing pens (for subject completed assessments) will be disposed or assigned to the subject during their stay and disposed upon discharge. Study equipment, such as but not limited to, pulse-oximeter, blood pressure equipment, IV pole, wires from ECG, clipboards, etc. will be disinfected prior to and after each use. Each room in which assessments/procedures are completed will be sprayed with disinfectant spray upon completion of assessments/procedures.

g. Based on pandemic conditions, other precautions may be put in place to mitigate exposure risk. The site, in coordination with and approval from Sponsors, would eliminate the need for subjects to comet to the site by performing remote visits with the use of video conferencing (i.e. telemedicine).

   i. Subjects would be supplied with necessary equipment (e.g. vital signs machine, scales for measuring weight) and trained to perform protocol specific activities at home.

   ii. For specific trials, subjects would be provided with enough Investigational Product so that self-administering can be performed at home under the supervision of a study staff member using video conferencing.

D. Notification of Potential Participant or Visitor Exposure

a. As soon as a site has been notified of a participant or visitors' potential exposure in the community, the Site Director, PI/Medical Director and the Chief Medical Officer must be notified immediately. The incident must be documented according to the sites process.

b. An evaluation will be conducted as to who should be communicated this information and next steps on prevention. The sponsor/CRO must be notified in a timely manner as to this information and to discuss next steps as it applies to participant safety and possible continuation/discontinuation in their trial, as applicable. Documentation should be maintained for all decisions and all notified parties. If the participant is active in a trial, then their symptoms must be documented as Adverse Events and further diagnosed upon a potential positive test/outcome. All instances must be reported to the IRB.

E. Remote Study Visits with Subjects

a. Upon the determination and input from the sponsor and investigator site, remote study visits may be an acceptable deviation to on-site visits, pending a participant agrees to do the visit in this manner. All correspondence must be documented and

filed in the Regulatory Binders as it applies to these decisions and subject source documents where applicable.

b. The sponsor and investigator site must review what the remote visits would entail in conjunction with the FDA Guidance provided for the pandemic in question. It is ideal but not always mandatory to obtain IRB approval prior to executing any procedures that would be in the best interest of a subject's safety and well-being (eg. continuing them in the study, terminating them from the study, the benefits of remaining on study drug, etc).

c. Investigational Product Dispensing may vary based on study, risk, or benefit to the subject. Special considerations must be made on a study by study basis as to whether IP may be mailed, picked up or dropped off. Further, if it is in the best interest of the participants safety and wellbeing to either continue them on study IP or not continue them on study IP, then this will be determined, and course of action documented. Temperature controls must also be considered. Once established this will be required to be outlined in the study plan developed by the sponsor and site, with IRB oversight at applicable intervals.

d. If safety decisions must be made prior to IRB approval or notification, then IRB notification must be done at the first available opportunity.

e. All decisions made must be documented *in detail* in the participants study files.

f. Subjects will be contacted on an ongoing basis by site personnel to review study compliance and monitor for adverse events.

F. General Employee Management

a. General Precautions to be Taken by Staff

i. All staff are responsible to contact their supervisor immediately if they have any symptoms of illness or exposure that may increase risk of infection. The supervisor will work with the appropriate team to be determined if they should remain home, for how long, and assigned responsibilities and tasks if

working from home is an option (dependent on illness). If a Supervisor cannot be reached, they are to contact the Chief Medical Officer (CMO).

ii. All staff are required to have their temperatures checked each time they present to the clinic for work. If a staff member is first to the clinic, they are responsible for recording their own temperature. Temperatures will be taken in the lobby or waiting room with an appropriate temperature recorder. Temperatures to be taken with a Non touch infrared thermometers. Should one not be available, other alternatives are acceptable with physician or NP approval. The staff member taking the temperature should wear protective gloves. If an individual's temperature is greater than or equal to 100.4 F, they will not be allowed into the facility pending further evaluation by the investigator.

iii. While employees are onsite, in addition to wearing their required Personal Protective Equipment (PPE) while working with biohazard materials, all staff should wear personal protective equipment inclusive of gloves, disposable gowns/lab jacket, and face masks during any interaction with study participants and strongly encouraged if near other employees (less than 6 feet apart). Should supplies be low, contact the CMO on further directive.

b. Modified Work Schedule

i. Schedules may be modified to limit exposure and infection risks and to adhere to governmental restrictions.

ii. In an effort to limit exposure and infection risks, depending on staffing availability, staff shifts will be modified such that there are 2 teams (Team A and Team B) working alternating shifts. Alternating shifts will consist of one team working on-site while the other team works remotely in one-week intervals. Teams will be divided so that there will be equal departmental representation on each team.

iii. If an employee's job allows for work from home full-time, this will be encouraged.

c. Remote Work Opportunities

i. If employees are required to work from home, Information Technology (IT) department will be contacted to confirm they have accessibility to all systems and hardware needed.

ii. Employees must discuss and work with their Site Directors on what work may be able to be taken home, and what type of Chain of Custody of those items must be employed. ***NOTE: Under no circumstances can original source data or any Protected Health Information (PHI) of our volunteers be removed from the facilities.***

iii. Should original source data or PHI of participants be needed to complete a remote task, then a protected electronic file (21 CFR Part 11 compliant) may be developed with restricted access so that the information may be uploaded for the purposes of data entry, data QC, etc. *A Note to File will be generated and filed in instances where remote data entry may be completed.*

iv. Any emails sent to external email addresses that contain PHI or confidential information must be encrypted. All documents containing PHI or confidential information should be shared using SharePoint or OneDrive. (See section vii)

v. Redaction of scanned documentation must be implemented to ensure appropriate protection of volunteers PHI. If documents must be printed at home to facilitate the work, then all copies must be saved and brought back into the clinic for destruction when able.

vi. Any data reviews or entries made must be verified against original source data upon returning to the clinic unless someone that is at the clinic can do the Source Data Verification on the employee's behalf.

vii. SharePoint online provides a solution to CFR 21, Part 11 Requirements. Security and data integration are provided by the following features:

Azure Active Directory Integration – Only authorized accounts can access the system

Prevention of unauthorized users. - SharePoint can prevent unauthorized users from accessing areas of the system, where electronic records are created and maintained. It is also possible to configure the record center with separate access controls.

Restrict access to system administration.
For additional safety, SharePoint can also restrict access to system administration and configuration by setting up security groups or permissions.

Protect Data Records
SharePoint can protect data records from deletion and enable their accurate retrieval. The SharePoint Information Management Policy feature is implemented, and retention policies are applied to various content types for a required period. Versioning is also setup to preserve copies of data records

G. Notification of Potential Employee Exposure

a. As soon as an employee learns of any potential for exposure to a person with a positive result as it relates to the pandemic, (e.g. grocery store, place of worship, etc), their Site Director and the Chief Medical Officer must be notified immediately.

b. An evaluation will be conducted as to who should be communicated this information and next steps on prevention. Documentation should be maintained for all decisions and all notified parties.

c. The employee must remain at home for a minimum of 14 days post exposure and be asymptomatic prior to returning to work.

H. Communication Management with Sponsors and CROs

a. All discussions and decisions made as they relate to the pandemic in question must be documented *in detail* and filed with the applicable studies. The participants that were active in those decisions must be identified, and signatures obtained when critical study impact decisions are made (e.g. Principal Investigator).

b. Considerations must be made by the site if any remote activities will be entertained by the sponsor/CRO to ensure continued monitoring, close out visits, Study Initiation Visits, etc. Accommodations and resourcing must be factored in to ensure realistic timelines may be achieved. See Letter I below on Management of Remote Sponsor/CRO Visits.

c. If ERG must decide to limit or even temporarily postpone activities at the clinical research site, a formal communication will be developed by Corporate Leadership to disseminate to the applicable clients.

d. The IRBs must be notified in all scenarios to changes in trial execution. If it is not feasible to obtain IRB approval prior to executing some of the new contingency plans or decisions, then approval must be obtained by the CMO to proceed.

I. Remote Sponsor/CRO Visits

a. Should remote monitoring, close out visits, audits, or meetings be requested, the Site Director will accommodate the requests unless other circumstances may prevent this (eg. hold on beginning new trials would yield postponement of an SIV). If Remote Monitoring Visits/Close Outs or Audits will be considered and accommodated, then refer to ***ERG Policy on Remote Study Monitoring During COVID-19*** for guidance.

References

www.Cdc.gov
www.fda.gov
www.who.int
www.advarra.com

Version History

New