



## **Evolution Research Group Risk Mitigation Response Plan COVID-19**

**Site: Finger Lakes Clinical Research (FLCR), Rochester,  
NY**

**Version: 02**

**Version Date: 02JUL2020**

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### **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 new information is learned or provided as applicable from organizations such as the World Health Organization (WHO), the Center for Disease Control (CDC), the Food and Drug Administration (FDA) and other regulatory bodies and local agencies to ensure consistency with expectations, rules and guidelines.

### **Plan:**

#### **A. General Visitor 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, fever, or any other symptom relevant to COVID-19 as guided by the CDC. If so, they should be rescheduled once they are feeling better, asymptomatic, and as approved by PI or Medical Director. 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) or another healthcare provider to seek treatment 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. Subjects will be reminded that any guests that accompany them will be requested to remain outside of the clinic.



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- b. If a volunteer requires transportation to the clinic and the clinic offers transportation, 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 will be made available prior to getting into the vehicle. The driver will take temperatures prior to entering the vehicle and document.
  - i. Note: If a driving service is utilized (e.g. Uber Health), volunteer will be instructed by site to not get into the vehicle and come to the site if they don't feel well. They will also be instructed to wear a face covering during the ride.
- c. Once volunteers arrive at the clinic, they will be required to have a temperature check prior to entering the facility and complete a health questionnaire (unless they were checked upon pick up from site transport). This information will be documented on the '*Site Visit Questionnaire for COVID-19*'. They then are required to be escorted to the nearest sink and instructed to wash their hands.
- d. Volunteers will only be taken to areas where they are required to be seen and will be instructed to wear a mask or face covering to get to the applicable area. Any additional PPE needed will be made available to the volunteer while onsite for their visit and replaced when necessary.
- e. Rooms where volunteers/study participants may be seen 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, etc.). Immediately after a volunteer is removed from a certain area, the room must be disinfected inclusive of any equipment used.
- f. Any deviations to any required study procedures must be documented, *in detail*, and rationale outlined as it relates to the pandemic.



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- g. COVID-19 testing for research participants may be performed by the sites' selected laboratory. Decision for testing will be made using a thoughtful approach and considerations applied as they relate to safety, protocol, sponsor requests or guidelines as noted in the 'Purpose' section of this document. The company's stance is as follows:
  - 1. COVID-19 testing will not be conducted at Screening or for Outpatient studies, unless required per sponsor. This may vary as new information becomes available.
  - 2. Testing may be considered for In Patient studies on a case by case basis or as required per sponsor at the time the subjects admit.

FDA guidance states that a listing of all participants affected by the COVID-19 related study disruption must be documented by unique subject number identifier and by investigational site, and a description of how the individual's participation was altered.

- h. Vendors or other visitors that come to the clinic will be instructed to remain in the lobby with a face covering. They will only be allowed to proceed into the clinic if they complete the '*Site Visit Questionnaire for COVID-19*' with questions and temperature check completed.

### **B. Inpatient Visit Management**

Inpatient trials are not conducted at this clinical research site location.

### **C. Outpatient Visit Management**

- a. Subjects are screened for potential exposure, symptoms and temperature upon arriving to the site in the waiting area. All subjects are provided a mask that must be worn for the duration of the visit and are required to wash their hands. When possible, and if allowed per protocol, caregivers are asked to drop patients off at the



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site and communicate any adverse events, changes in concomitant medication, or other relevant information with the study staff and PI via telephone.

- b. The study coordinator receives the subject in the waiting area and ushers the subject to the designated room(s) to complete visit procedures. Immediately after the subject leaves the room(s), all hard surfaces, writing instruments, and psychometric rating hardware are thoroughly cleaned with disinfectant.
- c. If a subject or caregiver are unable to come to the site to complete a scheduled visit due to COVID-19 restrictions or precautions, the study coordinator will schedule the visit to be conducted remotely following sponsor communicated guidance. All study staff involved will be notified regarding which procedures have been approved by the sponsor to be performed remotely for the given visit. All remote clinic visits will be communicated to the sponsor via email and clearly documented in the subject source. If applicable, protocol deviations will be clearly documented in the subject source.
- d. Due to the pandemic risk, site may also take additional precautions to limit the exposure of subjects to any potential of risks which may be present in the office (e.g. plexiglass barrier between raters and subjects during neurocognitive testing) While all viral contagion precautions are being taken, site may consider eliminating the use of the waiting room and requiring study participants to wait in their cars until their appointment. This will be determined based local status of the pandemic and discretion of Site Director and PI.
- e. If a subject's visit is greater than 4 hours, lunch may be ordered for the subjects. When received it will be brought to their exam room for consumption.
- f. Site may also conduct visits curbside when appropriate to limit office exposure. The procedures conducted curbside would be appropriate to that setting, including interviewing and self-assessments. The procedures to be conducted curbside would be determined on a case by case basis and are discussed with sponsor and IRB as applicable and when necessary.



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### **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, minimally 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 assessed upon a potential positive test/outcome. All instances must be reported to the IRB.
- c. Should a positive result be confirmed for a clinic volunteer/subject, the checklist for a '*Confirmed Positive Case of COVID-19 for a Research Participant*' checklist must be completed.

### **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 (e.g. continuing them in the study, terminating them from the study, the benefits of remaining on study drug, etc.).



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- 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, whether to continue study IP or not is in the best interest of the participants safety and wellbeing 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.
- g. Refer to '*ERGs Remote Subject Visits During COVID-19 Guidance*' document for further details

### **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 Site level Supervisor/Designee 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 taking their own temperature. Temperatures will be taken in



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the lobby or other designated entrance with an appropriate temperature recorder. Temperatures to be taken with 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 past the lobby/testing area 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 in accordance with safe work practices issued by OSHA and CDC (refer to *Guidance on Preparing Workplaces for COVID-19 by OSHA*). 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. Site staff that do not provide direct participant care may be instructed to work remotely, if able.
- iii. Employees may be assigned to a staggered shift to minimize exposure time to other employees and patients. On days that employees are not assigned to report to site work will be taken home. All employees will be assigned additional tasks such as training and recruitment telephone work take can be done from home.

Staff shifts may be modified as resourcing allows 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. Every effort will be made to divide teams so that each department may be represented.



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### 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:





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**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. A COVID-19 test may be requested of the employee where applicable.
- d. If a positive case of COVID-19 is confirmed for an employee, the site should execute the '*Confirmed Positive Case for COVID-19 for a Research Employee*' Checklist.



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### **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 documented approvals 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 (e.g. 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.



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### **Version History**

01: NEW – 22APR2020

02: Amended language in accordance with new information and site-specific changes in management of IP/OP visits (references to other internal guidelines, checklists, and tools being utilized)