

FCS Summary Business Continuity Plan

In accordance with the Centers for Disease Control and Prevention (CDC) recommendations, Frontage Clinical Services (FCS) will re-open clinic conduct activity with extensive policies and procedures in place to protect FCS staff and subjects engaged in clinical conduct activities that require face-to-face interaction in clinic settings.

General Facility

- FCS is actively practicing COVID-19 symptom recognition and monitoring.
- FCS is practicing social distancing throughout our facilities to mitigate subject and staff proximity to each other.
- FCS facility policies and practices including enhanced cleaning and disinfecting of the facility are in place to minimize exposures to respiratory pathogens including SARS-CoV-2 (COVID-19). Measures will be implemented before subject arrival, upon arrival and throughout the duration of the subject's in-patient visit.
- Comprehensive protective measures in FCS work settings to mitigate transmission of COVID-19 are documented in a separate manual " FCS COVID-19 GENERAL CLINIC GUIDANCE ". These measures include detailed procedures for screening, admission, study conduct and out-patient visits.

Subjects and Visitors

- FCS is employing COVID-19 testing for research subjects.
- Subjects and visitors such as monitors, sponsors or maintenance related personnel will be asked to complete the COVID-19 Exposure Questionnaire, have their temperature monitored prior to entry into the site, and be required to observe social distancing and wear a protective mask for the duration of their visit.
- Any study subject or visitor with a temperature of 100.4° F (or greater) or responding "yes" to any question in the questionnaire will not be admitted to the FCS facility until cleared by FCS medical team and/or their primary care physician.
- During in-patient stays, subjects will be monitored daily for temperature and signs or symptoms of COVID-19.
- During in-patient stays, subjects with a temperature of 100.4° F or greater, or with signs or symptoms of COVID-19 will be isolated to the designated COVID-19 assessment room or rooms for evaluation by the medical team.
- Each suspected study subject incident will be evaluated and treated on a case by case basis per medical advisement and CDC guidelines. CDC has issued guidance to provide a framework for the assessment and management of potential exposures to the virus that causes COVID-19 and implementation of safeguards and proper PPE based on a person's risk level and clinical presentation: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assessment-hcp.html>.

Employees

- FCS staff are temperature-monitored prior to entry into the site.

- FCS staff with a temperature of 100.4° F or greater, or with signs or symptoms of COVID-19 from self-monitoring at home will be instructed to stay home until cleared by their primary care physician. In addition, return to work criteria will be per CDC guidance: Discontinuation of Isolation for Persons with COVID -19 Not in Healthcare Settings - <https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html> and Public Health Recommendations for Community-Related Exposure - <https://www.cdc.gov/coronavirus/2019-ncov/php/public-health-recommendations.html>.
- FCS staff will wear appropriate personal protective equipment (PPE) for the job function that they are performing, in accordance with state and local guidance. Proper use of PPE will be per CDC issued guidance: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html>

FCS policies and procedures to assist sponsors in assuring the safety of study subjects, maintaining compliance with GCPs, and minimizing risks to study integrity are consistent with FDA issued “FDA Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Public Health Emergency” (updated 14May2020). We will continue to monitor our mitigation measures on an on-going basis as our knowledge of COVID-19 evolves. We look forward to assisting our clients in the important work they are doing while protecting the health and safety of our employees and study participants.