SOP Title: UF CTSI Clinical Research Center Screening for COVID-19

1. PURPOSE

To promote the safety of our Clinical Research Center (CRC) staff and vulnerable patient populations and to prevent the spread and infection of the COVID-19 virus, study visits cannot be scheduled or conducted in the CRC with participants who have tested positive for the COVID-19 disease or who are symptomatic at the time of the visit. All Research Participants and their Caretakers coming for study visits to the UF CRC will be screened upon arrival for history and symptoms of COVID-19 infection. Principal investigators and study teams are urged to pre-screen participants before scheduling and prior to coming to the CRC to avoid unnecessary travel or exposure.

2. SCOPE

This SOP applies to all Research Participants and their Caretakers who will be entering the UF CRC for study visits whether for room only or utilizing CRC staff. This includes Front Desk reception staff and UF CRC nursing staff.

3. RESPONSIBILITIES

The Administrative Assistant (Front Desk personnel) will greet participants on arrival to CRC and screen all Participants/Caretakers recent health and travel history. If the Participant and or their Caretaker answers “yes” to any of the questions on arrival, the Administrative Assistant will notify the CRC nursing staff. The CRC nurse will review the Research Participant and or Caretaker’s medical history and takes the Participant and or Caretakers’ temperature. If the participant or caretaker has or has had a history of known COVID-19 infection and/or are exhibiting a fever greater than 100.4 degrees Fahrenheit, then the Principal Investigator and/or study coordinator will be notified of the findings and asked to reschedule the study visit.

4. DEFINITIONS

AA- Administrative Assistant
CRC- Clinical Research Center
CRM- Clinical Research Manager
CTRB- Clinical Translational Research Building
CTSI – Clinical and Translational Science Institute
SOP- Standard Operating Procedure
UF- University of Florida

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5. PROCEDURES

A. Front Desk Screening

1. The AA will greet the Participant and Caregiver upon arrival to the CTRB.
2. The AA will provide a mask and Purell for the Participant and Caregiver to use.
3. The AA will implement the **COVID-19 Screening Questionnaire** (APPENDIX A).
4. If the Participant and or Caregiver answer in the affirmative to any of the questions regarding health and travel history, the AA will notify the CRC nursing staff before Participant and or Caregiver will be allowed to enter the CRC unit.*
5. The CRC nursing staff will evaluate the participant and or caregiver for evidence of infection or pertinent history and will take their temperature.
6. After the nurse's evaluation, if there are any indications of COVID-19 infection then the nurse will notify the Principal Investigator or member of the study team. The study visit will need to be rescheduled.

B. Infection Control

1. Participants and their caregivers are to be issued a mask and asked to use Purell prior to admission to the UF CRC.
2. The AA will provide a disposable paper adhesive participant badge.
3. Participants and Caregivers will be instructed to practice infection control by covering their mouth when they cough, to cough into their elbow, to wash hands and use hand sanitizer frequently and maintain safe distance from others as much as possible.
4. Participants may have only one Caregiver accompany them in the CRC. Additional visitors are not allowed.
5. Applicable signage will be posted at the entrance to CRC.

* COVID-19 guidelines are fluid and change with areas of community spread, please refer to the State of Florida guidelines for up to date information at the following link: https://floridahealthcovid19.gov/travelers/#:~:text=Governor%20DeSantis%20directed%20all%20individuals,in%20Florida%2C%20whichever%20is%20shorter.

Tracking History			
Action (Initial Approval, Amendments, Review, Reason for Change)	**Version No**	**Approval Date**	**Due for Review**
Initial Approval	**01**	**05/20/2020**	

Appendix A

UF CTSI Clinical Research Center

Screening Questionnaire for COVID-19

1. **Have you been tested for COVID-19 and had a positive test result? When? Were you treated? Has it been less than 14 days since treatment?**

2. **Do you currently have or have you had in the past 14 days?**
   *Fever
   *Cough
   *Shortness of breath
   * Vomiting or diarrhea
   *New loss of taste or smell

3. **Have you been in close contact (within 6 ft.) of anyone with a positive COVID-19 test result or suspected respiratory symptoms related to COVID-19 infection within the past 14 days?**

4. **Have you taken a cruise of any kind (ocean or river, international or domestic) or traveled to one of these areas with widespread or ongoing community spread of COVID-19 within the last 14 days?**

   *China, Iran, United Kingdom and Ireland
   *Europe
   *New York, New Jersey, Connecticut, Louisiana, Seattle; or
   *Miami-Dade, Broward, or Palm Beach Florida counties.

If the person answers yes to any of the above questions they will not be allowed in the CRC, their Study PI/coordinator will be notified and their study visit will need to be rescheduled.

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If the person is cleared with the questionnaire, obtain their temperature. Temperature must be less than 100.4°F or 38°C to proceed with the visit. If the temperature meets guidelines, inform the participant that they may enter CRC but they will be required to wear a mask at all times in public and patient care areas of the CRC and must practice social distancing.