

# Clinical Research Enterprise (CRE)

## Standard Operating Procedures

### Pre-Screening of Research Subjects for COVID-19

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**Revision History:**

**Version**

**Effective Date**

**Description**

#### Purpose

The purpose of this SOP is to describe the process for pre-screening subjects coming to UAB for a clinical trial visit.

#### References

- a. UAB Sample Script for Participant Phone Calls 05152020
- b. What you can expect during a study visit in the Era of COVID\_UAB 05152020
- c. COVID-19 Screening form

#### Scope

This SOP applies to all UAB staff members involved in clinical trial visits

#### Allowable Exceptions

This SOP is to be followed without deviation.

#### I. Details

- I. 24 hours prior to a subject's arrival at UAB for any clinical trial visit, they should be contacted and pre-screened for any symptoms or possible exposures to COVID-19
- II. All subjects should also be provided the "What you can expect during a study visit in the Era of COVID" document prior to any study visit.
- III. If the subject answers NO to all of the pre-screening questions, they should be reminded that if any symptoms arise prior to their visit to stay home and contact coordinator to reschedule their visit
- IV. If the subject answers YES to any of the pre-screening questions and/or has a temperature of 100.4 F or above, they should be instructed to contact their primary care provider and study visit should be rescheduled.

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### **II. Procedures**

#### **I. Pre-Screening Contact for COVID-19**

- a. 24 hours prior to any study visit, subject should be contacted for Pre-Screening for COVID-19 symptoms.
  - b. If unable to reach subject after 3 attempts, study visit should be rescheduled.
  - c. Subject should be provided “What you can expect during a study visit in the Era of COVID” prior to or during the Pre-Screening contact.
  - d. Contacting person should follow “UAB Sample Script for Participant Phone Calls 05152020” documentation provided during phone call.
  - e. Documentation of Pre-Screening call should be recorded on “COVID-19 Screening Form” source and filed in subjects study chart
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