C3PO
Clinical Trial of COVID-19 Convalescent Plasma in Outpatients

Steps to obtain 15- and 30- day assessments

Timing of Visits and Protocol Specified Windows:

15-day: 15 days from randomization (-1 day, +1 days)
30-day: 30 days from randomization (-1 days, +3 days)

Nonetheless, please pursue the 15-day visit until the time the 30-day visit window opens, and the 30-day visit until 3 days after the 30-day time point. If the symptom inventory is obtained outside of the 15-day or 30-day window, subjects should be informed that their responses should be based on their current health status at the time of the assessment. This applies to the Treatment Blinding Assessment as well. Sites should only collect blood samples during the protocol specified visit windows. Blood should not be collected past a visit window.

1. **At the time of enrollment, obtain a medical record release**, signed by the subject, to facilitate acquisition of local and outside medical records during the 30-day course of trial participation. The subject can complete the medical release form at the time of follow-up if a release was not previously obtained. Sites should use their own medical record release template, leave the hospital blank, and request access to medical records from the date of informed consent through 33 days (end of follow up).

2. **Schedule the 15-day and 30-day follow-up visits prior to ED discharge**. Use the study calendar in WebDCU™ to assist in identifying expected visit dates for day 15 and day 30 visits.

3. **Remind the subject** that they will be contacted by a Central Call Center in 2 days and will continue to be contacted by the Call Center every other day for 2 weeks. Let them know that calls will be coming from a 650 area code so they do not screen out the call. Let the subject know that these calls are important to find out how they are feeling until they return for their Day 15 visit.

4. Prior to the Day 15 visit (suggest Day 10), **call the subject** at the telephone number(s) provided by the subject to remind them of their upcoming visit. If the subject is not willing to attend the follow up visits, attempt to collect the follow up data over the phone, even if the assessment date is out of the window.

5. If attempts to contact the subject are unsuccessful, **contact the alternative contacts** provided by the subject to inform them of the upcoming visit.

6. If the site is unable to reach the subject or alternative contacts by phone:
   - **text and/or email** the subject.
   - **review the subject's CRF Binder** in WebDCU™ to see if the Central Call forms during Days 2-14 have been completed.
   - **reach out** to the Stanford Call Center to see if they can relay the message to the subject at their next call (the call center will reach out to the site study coordinator if they have not had any contact with the subject)

7. If the prior steps are unsuccessful, **send a letter by mail**.

8. If this is unsuccessful, **check the medical record and local obituaries** to assess interim history and vital status.

A subject should not be declared lost to follow up until a concerted effort is made to collect all adverse event information and affirmation of the adverse event assessment form is completed. Attempts to contact subjects and review medical records and vital status records for this information should continue during the duration of the C3PO Trial.

Subjects for whom the primary outcome can be determined by any means are not lost-to-follow-up, even if that subject does not return for blood draws or assessment of secondary endpoints. Study teams should use all available methods to determine the primary outcome: direct communication with the subject, communication with their family or informants, review of medical records, review of public records, etc. Study teams will need to discuss any proposal to consider a patient lost to follow up with the Data Coordinating Center and Clinical Coordinating Center.