

CLINICAL TRIAL OF COVID-19 CONVALESCENT PLASMA IN OUTPATIENTS





Stats

- Released to Enroll....37
- Upcoming Sites......17 Sites Screening......26**
- Screen Failures.....270

** If your site has been released to enroll and you have not yet entered a screen failure in WebDCU, please do your best to do so asap! All sites should enter SFs <u>every day or so</u>.

Congratulations!

We are extremely proud of the following sites who have enrolled subjects

Site	Enrolled
Stanford	6
Harbor - UCLA	6
UCSD - La Jolla	5
Jackson Memorial	4
Health Partners Methodist	4
University of Florida Shands	3
Cooper University Hospital	3
Spectrum Health	2
Mercy St. Vincent	2
Oregon Health & Science University	1
Baystate Medical Center	1
Cedars Sinai	1
University of Iowa	1

Dates To Remember:

Study Coordinator Meeting Oct 6 at 1pm ET SIREN Steering Committee Oct 28 at 12pm ET

Updates and reminders....

- **Convalescent Plasma:** The CCC will be responsible for all CP ordering and ensuring you have inventory available. When CP is shipped from Vitalant to your site, the site primary study coordinator and blood bank designee will receive an email with the packing slip attached, which will contain individual unit information. The email will come from Glenn Polanski (most often). Please make sure that this email does not go directly to your spam box.
- **Informed Consent:** To access your consent form, please always use the URL link you were provided in the site notification with the subject "C3PO Released to Enrollment". That shortened link typically starts with bit.ly/

Prior to giving the ICF to the subject, ensure that you are using the right version of the consent form by confirming that the site PI name and site address are visible just below the title.

Return Visits:

Day 15: 15 days from randomization (-1 day, +1 days) Day 30: 30 days from randomization (-1 days, +3 days) **Important** 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.

Medical Release: At the time of enrollment, obtain a medical record release signed by the subject to facilitate acquisition of local and outside medical rec-

ords 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.

Biospecimen shipping: All shipping will be arranged by World Courier. You will only be required to provide the frozen samples to them. Given the costs of shipping samples, we would like to restrict the number of times you ship samples to our central biorepository to 1-2 times during the duration of the study. Please hold on to the serum and plasma samples you collect until the end of the study if at all possible.



WebDCU[™] Data → Information → Knowledge

- Please remember to acknowledge receipt of kits and CP in WebDCU when they arrive at your site. Not doing so can block a randomization.
- Enter CRFs within 5 days of visit date (There has been a delay in entering F181 Biospecimen Collection and F502 Study Administration forms).
- Report SAEs within 24 hours as weekly safety reports are being provided to the DSMB.
- Form 505 Subject Follow-Up will soon be added to the database. It will allow sites to enter information on subject contact, specifically when there is no AE to report.
- If an eligible potential subject declines consent please provide their reason for declining consent in the comment box that can be found on the screening log.

Stanford REDCap

Remember to have the subject register for the central caller follow-up database BEFORE they leave the Emergency Department.

Explain to your subjects the importance of responding to emails and phone calls from a 650 area code!

OFFICE HOURS

Mon 4pm ET & Wed 9am ET

Meeting URL:

https://bluejeans.com/600577581

Meeting ID 600 577 581

Want to dial in from a phone?

Dial one of the following numbers:

- +1.312.216.0325 Chicago
- +1.202.795.3352 Washington DC
- +1.408.419.1715 San Jose







NIH SIREN Emergency Trials Network





