C3PO Today

November 16, 2020

Clinical Trial of COVID-19 Convalescent Plasma in Outpatients

160

 # ENROLLED

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DATES TO REMEMBER:

Study Team Meeting Nov 18@ 12PM ET

SIREN Steering Committee Nov 25 @ 12PM ET

RELEASED TO ENROLL IN NOVEMBER

University of Louisville Hospital

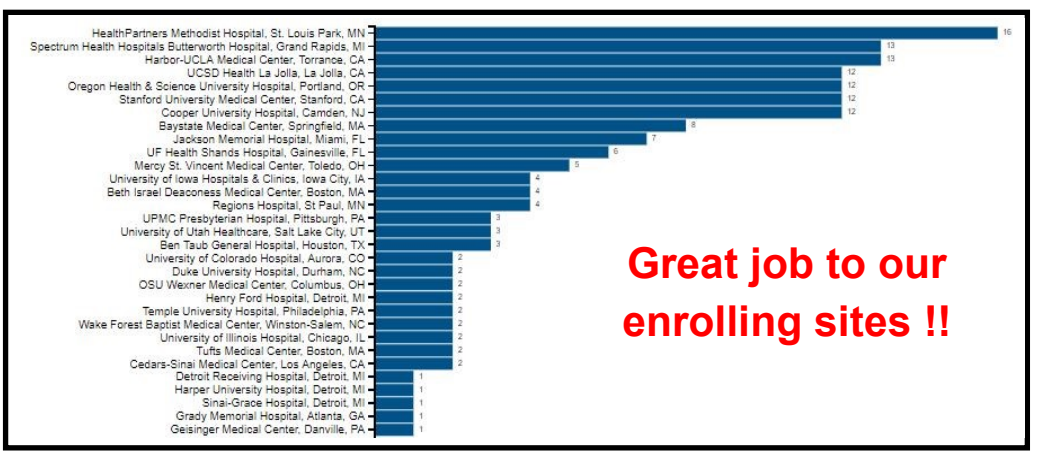
SUNY Downstate Medical Center

Einstein Medical Center

RUSH University Hospital

William Beaumont Hospital Royal Oak

Loma Linda Medical Center



Great job to our enrolling sites !!

Updates:

Protocol V4.0 changes approved 11-4-20
(see C3PO website for documentation)

Ancillary Study: To examine B and T cell responses in 100 C3PO participants and determine how receipt of CP affects the adaptive immune response to SARS-CoV-2. Requires PBMCs to be processed and cryopreserved at a central laboratory within 24 hours of collection. Please contact c3po-contact@umich.edu if your site is interested in participation or would like more information.

Eligibility Clarification: Adults presenting to the emergency department with **their first episode** of symptomatic, laboratory-confirmed COVID-19 illness.

Compensation clarification: Subjects may be eligible for compensation for their time and travel/parking at any study visits including the enrollment visit, based on local institution practices.

New risk factors for severe disease: The CDC has now included pregnancy and smoking (current or former cigarette smoking) as risk factors for severe COVID illness. Patients with these risk factors are eligible for enrollment in C3PO. See MOP section 3.2.

Enrollment reminders:

Check eligibility and patient willingness to enroll one last time right before randomizing. Be sure the clinical team has not changed their mind about discharging the patient. Some patients may be restless and eager to leave the ED. Inform the patient that the time from randomization until ED discharge is about 2 hours. You should randomize by submitting the enrollment form right before you order either plasma or placebo. It is better to have a screen failure than to randomize someone who does not stay to get the intervention or who is really not eligible.

Consider ways to make the long ED stay more tolerable such as iPad to watch movies, a meal or snacks, validated parking, a reminder that a chance to prevent a more severe illness/ return ED visit or hospitalization over the next two weeks is also good potential return on spending a few more hours in the ED.

Consenting Non-English Speaking Subjects:

E-Consent can only be used for English and Spanish speaking subjects. An Advarra approved Short Form and the site approved paper consent should be used by an interpreter to consent subjects in their native language. The interpreter should also sign the paper long form.

WebDCU™

Data → Information → Knowledge

- Delay in entering F502 Study Infusion Administration and F181 Biospecimen Collection. We typically have a 5-day window to enter case report forms, but we ask that these forms be entered ASAP as it can cause delays in randomizations.
- There has also been a delay in entering F501 Affirmation of Adverse Event Assessment. We ask that this form be entered within 5 days of the visit date.
- Enter SAEs within 24 hours of discovery. If patient has not been discharged from the hospital, please dismiss the rule violation on Q25: Date of Discharge by clicking on the blue and white icon beneath the warning. Please add a response, such as “Patient has not been d/c”. Once patient has been d/c, edit the form and add the d/c date.
- Be sure to initiate the Stanford REDCap registration for patient follow-up while the subject is in the ED. Try to complete the subject’s registration step with them to ensure it is completed before they leave the ED.
- Day 15 blood draw time window is -1 day, +1 days from randomization. If subject is unable to come in for their Day 15 blood draw, please be sure to complete the remainder of the Day 15 visit CRFs over the phone.

Supplies: CP, Kits and Labels

CP Inventory: Monitored by the CCC and replenished as needed. Accurate inventory counts are dependent of data entry of Form 502 Study Infusion Administration—please enter this form promptly!

Remember to return the shipping box to Vitalant per the instructions provided on the packing slip

Contact Carol Van Huysen at cvanh@umich.edu for questions or concerns

Biospecimen Kit Inventory: Sites will be put in the queue for replacements when inventory reaches 12 kits on hand. Replacement may take 7-10 days.

Contact C3PO–sample@umich.edu for requests, questions or concerns.

Placebo Labels: The CCC will no longer be providing placebo labels to the sites. You will be able to print your own and only what you need using the templates provided in the Toolbox under Resources for the Study Team. Ordering information for printable labels is also included.

Contact c3po-contact@umich.edu. for questions

New Resources

The following Advarra-approved Subject Resources were posted to the Toolbox > Resources for Subjects.

NOTE: The Spanish version of these materials are awaiting Advarra-approval and will be posted once approved.

Enrollment Flyer

Enrollment Trifold Brochure - **inside** and **outside**

Note: Enrollment flyer and brochure have the same content.

Flipbook *(pictures and captions* describe participation in the study)

Subject Discharge Instructions

OFFICE HOURS

Mon 3pm ET & Wed 9am ET

Meeting URL:

https://bluejeans.com/600577581

Meeting ID 600 577 581

NIH National Heart, Lung, and Blood Institute · University of Michigan · NIH SIREN Emergency Trials Network · UPMC Life Changing Medicine · MUSC Medical University of South Carolina · Stanford Health Care Stanford Medicine