

OHSU SIREN NETWORK NEWS

Issue: November 2020

CALENDAR

11/12 3-4pm ET Finance Committee Call – Bluejeans link in e-mail

11/18 12-1pm ET Steering Committee Meeting – Bluejeans link in e-mail

11/18 1-2pm ET Journal Club – Bluejeans link in e-mail

12/1 1-2pm ET Study Coordinator Meeting – Bluejeans link in e-mail

Contact us: Jenny Cook, Coordinator, 503.494.1230 <u>cookjen@ohsu.edu</u> <u>OHSU SIREN Website</u>

Twitter: <u>@OHSU_CPREM</u>

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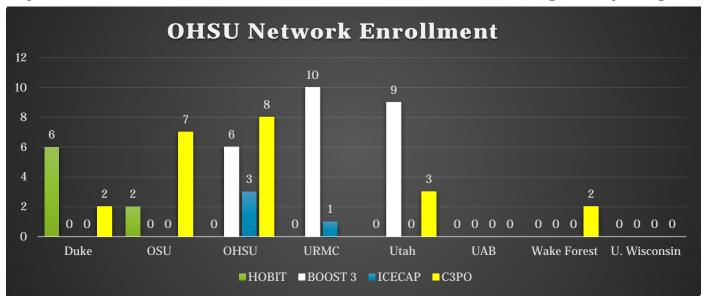
A NOTE OF THANKS

In a year that has been full of chaos, uncertainty, loss, 'new normals', stress, civil unrest, and challenges most of us never dreamed we might face; we want to take a moment to say thank you to each and every member of our network. We know how overwhelmed or exhausted many of you have felt this year and are likely still feeling. We feel that too. And yet, through all this strife, you have all continued to connect with us, to work hard for our common goals, and achieve excellence in research. Our network is one of the top performing Hubs across all studies, which we have only achieved through the hard work and dedication of each site, each study team, each individual. While we wish we could get together and celebrate our achievements, 2020 has clearly had other plans, so for now we will have to suffice by saying THANK YOU.



OHSU NETWORK PERFORMANCE AT A GLANCE

Great work keeping our enrollment numbers strong across trials. To date we have collectively enrolled 59 subjects in SIREN network trials! **That's 27 enrollments since our October report, way to represent!**



C3PO NEWS & UPDATES

- C3PO enrollments: 130 (Target enrollment 600)
- OHSU Network Enrollment: 22 (17% of total enrolled subjects)
- <u>Version 4 of the C3PO Protocol</u> was released on 11/5/20. Please review the changes. This update primarily added the optional ancillary study.
 - o C3PO Ancillary Blood draw information sheet
- The current enrollment rate is approx. 20 subjects/week which means we currently anticipate this study to be completed by April 2021. The first interim analysis will be after 200 subjects have been enrolled.

BOOST 3 NEWS & UPDATES

- BOOST 3 enrollments: 90 (Target enrollment 1094)
- OHSU Network Enrollment: 25 (27% of total enrolled subjects)
- <u>BioBOOST Protocol Released</u>
- BioBOOST Milestone Checklist Released
 - Kudos to all OHSU network sites for getting started on their BioBOOST Readiness Checklist.
 Don't forget you can review your site's readiness tasks left in WebDCU by navigating to the
 BOOST 3 tile →site management→Readiness Report BioBOOST

HOBIT NEWS & UPDATES

- Enrollment: 51 (Goal:200)
- OHSU Network enrollment: 8 (15% of total enrolled subjects)
- BioHOBIT Investigator meetings Considering participating in BioHOBIT? The PI and Primary Study Coordinator from each site will be required to attend one of the offered times. Other study team member are welcome to attend as well.

- Monday November 9, 10:00am 12:00pm (Eastern)
- Thursday November 12, 3:00pm 5:00pm (Eastern)
- On 11/2 you should have received the NOA, sub recipient info, and milestone document for BioHOBIT. If you did not and need a copy, please e-mail Jenny <u>cookjen@ohsu.edu</u>
- <u>Dive Log Version 6 now available</u>

ICECAP NEWS & UPDATES

- Enrollment: 56 (Goal: 1800)
- OHSU Network Enrollment: 4 (7% of total enrolled subjects)
- Congrats to Utah who is now released to enroll in ICECAP!
- Is your site still working to bring ICECAP online? Can we help you? Have you run into roadblocks? Please reach out to Jenny and Mo if we can help you in any way.

GLOSSARY OF FREQUENTLY USED ABBREVIATIONS

CCC = Central Coordinating Center (i.e. University of Michigan) EFIC= Exception from informed consent CC = Community Consultation PD = Public Disclosure cIRB = Central IRB (in this case Advarra)

C3PO MECHANISMS SUB-STUDY

Overview

We are launching a study of immune responses in 100 C3PO participants to measure B and T cell responses to determine if receipt of convalescent plasma affects the adaptive immune response to SARS-CoV-2. These studies require collection of peripheral blood mononuclear cells (PBMCs). PBMCs can be processed and cryopreserved within 24 hours of collection at a central laboratory. The specimens will be shipped to and processed at Vitalant Research Institute (VRI) in San Francisco.

Study procedures at participating sites

- Specimen collection lab shipper kits include EDTA tubes, Specimen Collection Form, Sample ID labels, and return FedEx waybill will be sent to you from VRI. These are different from the lab kits you get from the University of Pittsburgh.
- Collection kits will be stocked at participating sites and can be replenished on request from VRI.
- Consent for the sub-study will be included as an opt-in box on the main consent form.
- Collect two additional 10 ml EDTA tubes at the baseline (pre-intervention), day 15, and day 30 time points during the regular study blood draw.
- Fill out a brief form listing study ID, time and date of draw, FedEx tracking number, and phlebotomist name.
- Scan and email phlebotomy form to VRI staff.
- Completed Specimen collection shipper kits are shipped the day of collection to be received within 24 hours of collection by VRI in San Francisco.
- Given the requirement for samples to be received and processed by the lab within 24 hours of collection, collections must occur in time for completed kits to be picked up by FedEx the day of collection in order to be received the next morning at the central lab, collection of these samples will occur only on Sunday – Thursday?

For questions please contact Philip Norris at VRI (<u>pnorris@vitalant.org</u>), Clifton Callaway (<u>callawaycw@upmc.edu</u>), or Frederick Korley (<u>korley@med.umich.edu</u>).