



OHSU SIREN NETWORK NEWS

Issue: April 2019

CALENDAR

4/9 OHSU all site call

4/11 1pm EST HSP Working group

4/11 3pm Finance Committee meeting

4/17 1pm EST SIREN Journal Club [click here](#) to join

4/24 12pm EST SIREN Steering Committee - Bluejeans link in e-mail

5/7 1pm EDT SIREN Study Coordinator – Bluejeans conference link in e-mail

[SIREN CCC Events Calendar](#)

Contact us: Jenny Cook, Coordinator, 503.494.1230
cookjen@ohsu.edu
[OHSU SIREN Website](#)

ANNUAL REPORTING

- ✓ Thank you to all sites for providing summaries for your sites! Our annual report has been submitted, and we appreciate your time and help.

REQUEST FROM THE CCC

Your help by documenting in your email subject line the following pieces of information would be sincerely appreciated!
Subject line: Study name: Your site name – nature of your email (briefly in a few words).
Additionally, including a signature with a telephone number at the bottom of your email is very useful.
-Thanks from the SIREN CCC team

BOOST 3 NEWS AND UPDATES

- Has your site completed the Milestone 1 tasks yet? We will be reaching out to each site soon for an update on your progress on pre-study tasks. Need help? Our team is here to support you, so e-mail us anytime!
- MOP released – download your copy from the [SIREN website](#)
- SAEM: Details coming soon on the OHSU Network gathering @SAEM
- New [SIREN cIRB SOP](#) posted

ALL SITE QUARTERLY CONFERENCE CALL APRIL 9 10AM PT

Please have at least 1 representative attend our quarterly meeting!

1. Web/Mobile Audio and Video Conferencing

<https://nexus.ohsu.edu/index.html> Click the "Join meeting as a guest" button

Meeting ID: 567230681 Passcode: 1230

2. Phone Audio-Only 503-444-9598 Meeting ID: 567230681#

Passcode: 1230#

3. iPhone One-Touch Audio Call 503-444-9598,,,567230681#,,1230#

WEBDCU HELPFUL HINT

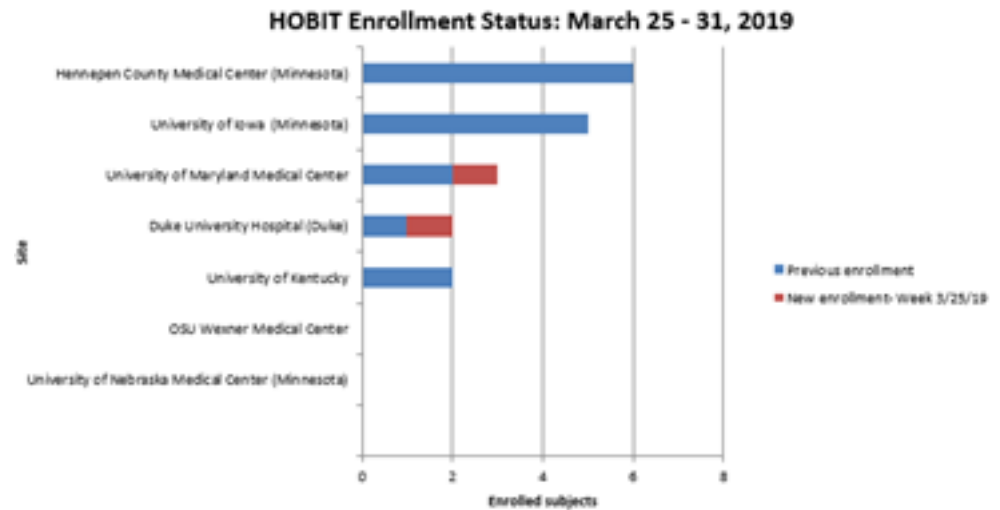
eDOA – When completing your DOA – you must mark “DOA Complete=Yes” to submit it for review by the CCC. Many of the forms in WebDCU allow you to do this (which essentially leaves the form pending or ‘in progress’ until you click ‘yes’ to submit it). If you have any forms that are ready for submission or your think should have been reviewed already, it’s always a good idea to double check that you have clicked the correct radio button to submit.

6				<input type="radio"/> PI	<input type="radio"/> HPI	<input type="radio"/> PSC	<input type="radio"/> SSC	<input type="radio"/> RDC	<input type="radio"/> HSC	<input type="radio"/> BOA	<input type="radio"/> CI	<input type="radio"/> A	<input type="radio"/> B	<input type="radio"/> C	<input type="radio"/> D	<input type="radio"/> E	<input type="radio"/> F
				<input type="button" value="Add New Row"/>													
Study Roles	R1 - Principal Investigator R2 - Hub Principal Investigator R3 - Primary Study Coordinator	R4 - Secondary Study Coordinator R5 - Regulatory Document Coordinator R6 - Hub Program Manager	R7 - Blinded outcomes assessor R8 - Co-Investigator														
DOA Responsibilities	A - Overall responsibility for the trial B - Internal SIREN Hub/Spoke verification C - EFIC Activities (CC/PD) D - Maintain Regulatory Compliance in WebDCU E - Ongoing Clinical Team Training	F - Obtain Informed Consent G - Complete CRFs/respond to queries H - Moberg Data Collection/Transfer I - Assess/Report AEs J - Clinical Subject Monitoring	K - Subject Tracking/Follow Up L - Administer Blinded Outcomes Assessment M - CT Scan Accountability														
7	Submit to Regulatory Document Manager for review		DOA complete.	<input type="radio"/> No <input checked="" type="radio"/> Yes													
8			Review status	Pending													

PS – this is a good rule of thumb to follow when e-mailing our site as well. Communications will only need to increase as we move forward with network studies, so please be diligent about clearly identifying these important bits of info so we can keep communications as helpful and efficient as possible.

ONGOING TRIALS

- HOBIT
 - A short enrollment suspension occurred in March from 3/5-3/12 due to “...an incident that took place at one of our monoplace sites during routine device maintenance of the Ohmeda battery pack. No subjects were involved.”
 - Enrollment: 18 subjects (Goal:200)
 - Kudos to Duke on your 2nd enrollment!
 - [New FAQ's available](#)



WORKGROUP UPDATES

The Human Subjects Protection workgroup last met in February. Some updates:

- They are working on some ongoing manuscripts from ESETT, PROTECT EFIC experience. One such paper is iPad Data from the POINT trial
- Also will be submitting an Administrative Supplement to Central IRB review of local context in emergency research. Empirical ethics study: The existing aims of the project are
 - (1) to explore stakeholder perceptions regarding the purpose and current practice of IRB review of local context,
 - (2) to refine stakeholder consensus-driven measures for review of local context in the setting of EFIC research, and to
 - (3) to test, using this empirical ethics methodology, local and centralized IRB performance by comparing IRB reviews performed locally during startup of an actual EFIC trial conducted in NETT and PECARN with simulated reviews performed by a CIRB panel.