**July 1, 2021**

4-5:00 PM EST

RHO Implementation Monthly Investigator Call Minutes

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| **Invitees/Attendees:** | | | | | |
| Dr. Larry Rhein, Principal Investigator | ✓ | Boston Children’s Hospital | ✓ | Maria Fareri Children’s Hospital | ✓ |
| Heather White, Project Coordinator | ✓ | Children’s Hospital of Philadelphia | ✓ | Massachusetts General Hospital | ✓ |
| Lindsey Simoncini, Research Assistant | ✓ | Cincinnati Children’s Hospital | ✓ | Nationwide Children’s Hospital |  |
| Maria Matoshi, Research Assistant | ✓ | National Jewish Health, Colorado | ✓ | Peyton Manning Children’s Hospital |  |
| Arkansas Children’s Hospital | ✓ | Dartmouth-Hitchcock Medical Center | ✓ | U. of California, San Diego | ✓ |
| U. of Kentucky Children’s Hospital | ✓ | University of Maryland | ✓ | Vanderbilt |  |

**Site Trainings**

* All Wave 1 site trainings have been completed.
* 4 out of 8 Wave 2 site trainings have been scheduled.
* Masimo is coordinating times to meet with sites’ home care companies. Heather presenting to acute home care’s on July 21st.

**IRB/regulatory**

* Due to delays in SMART IRB submissions of wave 2 sites start the process with your IRB in the meantime.
  + You may also choose to complete your IRB as an independent site.
* If your IRB is requiring written informed consent, do not cede approval to UMMS.
* Heather completed the protocol for referral hospitals that require a separate IRB for providing VON data. Reach out to her if you need any help.
* pSite forms will be disseminated once an individual site IRB has ceded approval to UMMS.

**Home Care Companies**

* Masimo will help ensure that each site has 2-3 home care companies providing RAD 97.
* 57% of sites meet our target goal.
* National home care companies such as Lincare, Apria and Promptcare are interested in joining at the smaller branch level. More updates to come.

**Site progress on Implementation Start-Up**

* Please send your current list of study personnel and CITI certificates to Maria Matoshi as part of the regulatory documents’ requirement.
* Refer to Site Progress table on Page 4

**REDCap User Access Groups**

* Lindsey will send out the instruction sheet on how to fill out REDCap forms. It will also be included on our website:

<https://www.umassmed.edu/rho-program/>

Login: RHO

Password: Oximetry14

* Notify Lindsey and Heather once you have been granted UMass REDCap approval to be added to your site’s data access group.

**Timing of Data Collection**

* The goal is to send VON and additional outpatient variable data within 3 months of onset of implementation.
* Implementation data:
  + Screening and eligibility form should be filled out prior to NICU discharge.
  + Demographics form should be filled out around the time of NICU discharge. Pulmonary Hypertension diagnosis is particularly important since it changes the RHO algorithm for weaning.
    - We are going to add a diuretics section to this form.
  + Home Oxygen Data Form will be filled out in real time by your DCC. Important to provide response on action taken to oxygen flow rate.
  + Adverse events will be followed for 6 months post HOT discontinuation. Adverse events include both respiratory and non-respiratory emergency department visits, urgent care visits, and hospitalizations.
    - Dates and reminders of this data collection will be provided in your sites monthly report.

**The RHO Algorithm**

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| --- | --- | --- |
| **Figure 1: RHO OXYGEN WEANING PARAMETERS** | | |
|  | **STANDARD**  **OXYGEN MANAGEMENT GROUP** | **RHO**  **OXYGEN MANAGEMENT GROUP** |
| CRITERIA FOR **INCREASING**  O2 FLOW RATE | INABILITY TO MAINTAIN  **O2 SAT >93%**  AT PATIENT’S CURRENT O2 LEVEL  FOR 20 MINUTES IN CLINIC  VISIT CHALLENGE | INABILITY TO MAINTAIN  **O2 SAT >93%** FOR  >95% OF RECORDED TIME |
| CRITERIA FOR **MAINTAINING**  CURRENT  O2 FLOW RATE | ABILITY TO MAINTAIN  **O2 SAT >93%**  AT PATIENT’S CURRENT O2  BUT  UNABLE TO MAINTAIN  **O2 SAT >93%**  AT WEANED FLOW RATE  FOR 20 MINUTES IN CLINIC  VISIT CHALLENGE | ABILITY TO MAINTAIN  **O2 SAT >93%** FOR  >=95% OF RECORDED TIME BUT  UNABLE TO MAINTAIN  **O2 SAT >96%** FOR  >=95% OF RECORDED TIME |
| CRITERIA FOR **WEANING**  O2 FLOW RATE | ABILITY TO MAINTAIN **O2**  **SAT >96%**  AT WEANED FLOW RATE  FOR 20 MINUTES IN CLINIC  VISIT CHALLENGE | ABILITY TO MAINTAIN  **O2 SAT > 96%** FOR  >=95% OF RECORDED TIME |
| \*\* RHO pass and fail will be determined by assessment of recorded oximetry. For each episode of transmitted data, a minimum of 1500 minutes of recorded data, will be required for analysis to make any determination.  \*\*\* Infants followed by the RHO program will also receive monthly in-clinic weaning attempts | | |

**Next Investigator Meeting will be on August 5th at 4pm EST**

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| **Implementation Wave** | **Site #** | **Site Name** | **Contract Executed** | **cIRB Approval** | **Local IRB Approval** | **Regulatory Documents** | **pSite Communication Plan Agreement** | **REDCap Access** | **Site Training Completed** | **Site Implementation Date** | **First Enrollment Date** | **Downloading Schedule** |
| **Wave 1** | 102 | Boston Children's Hospital | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | 6/1/2021 |  | M/T |
|  | 106 | Dartmouth-Hitchcock | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | 6/1/2021 |  | T/F |
|  | 107 | Maria Fareri Children's | **ᴏ** | N/A | **ᴏ** | **ᴏ** | N/A | **ᴏ** | **ᴏ** | 6/1/2021 |  | M/T |
|  | 108 | Massachuesetts General Hospital | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | 6/1/2021 |  | M/T |
|  | 113 | University of Maryland | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | 6/1/2021 |  | M/T |
|  | 114 | Vanderbilt | **ᴏ** | N/A | **ᴏ** | **ᴏ** | N/A | **ᴏ** | **ᴏ** | 6/1/2021 |  | T/F |
| **Wave 2** | 101 | Arkansas Children's Hospital | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | 8/1/2021 |  | TBD |
|  | 103 | Children's Hospital of Phil. | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | 8/1/2021 |  | TBD |
|  | 104 | Cincinnati Children's Hospital | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | 8/1/2021 |  | TBD |
|  | 105 | National Jewish Health | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | 8/1/2021 |  | TBD |
|  | 109 | Nationwide Children's Hospital | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | 8/1/2021 |  | TBD |
|  | 110 | Peyton Manning Children's Hospital | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | 8/1/2021 |  | TBD |
|  | 111 | U. of California, San Diego | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | 8/1/2021 |  | TBD |
|  | 112 | U. of Kentucky Children's Hospital | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | **ᴏ** | 8/1/2021 |  | TBD |