

ACT NOW Weaning Trial Investigator Meeting

March 9-10, 2020

William H. Bolger Center

Investigator Meeting Agenda

Overall meeting objective: Train all participating sites' primary staff on Weaning's protocol and procedures for the purposes of correct and ethical conduct of the trial across the ISPCTN and the NRN.

By the end of this meeting, all attendees will be able to:

Objective #1: Implement all protocol-specific procedures needed to conduct the Weaning trial.

Objective #2: Identify strategies to recruit, consent/assent, and retain participants in the Weaning trial.

Objective #3: Implement good clinical practices and how to handle and report safety data for the Weaning trial.

Objective #4: Discuss any issues or concerns clinical sites may have about the trial or procedures, and address them accordingly.

Monday, March 9, 2020

Time/Location	Topic	Presenter/Moderator
8:00 A.M. – 8:30 A.M.	Registration	
8:30 A.M. – 8:45 A.M.	Welcome <ul style="list-style-type: none">- Orientation to ISPCTN and NRN- Meeting logistics- Meeting goals	<u>Weaning Operational Pls:</u> Abhik Das Brian Smith Jessica Snowden
8:45 A.M. – 9:15 A.M.	Protocol Training Session 1 <ul style="list-style-type: none">- Background/Rationale for the trial, NNNS exams and Follow Up- Hypothesis and primary outcome- Equipoise	<u>Protocol Chair:</u> Abbot Laptok
9:15 A.M. – 10:00 A.M.	Protocol Training Session 2 <ul style="list-style-type: none">- Identification of patients- Recruitment (short term and long term strategies)- Marketing- Inclusion and exclusion criteria	<u>Protocol Co-Chair:</u> Adam Czynski
10:00 A.M. – 10:30 A.M.	Break	
10:30 A.M. – 11:15 A.M.	Protocol Training Session 3 <ul style="list-style-type: none">- Presenting the study to mothers/caregivers- Consent	Erica Oliveira

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Time/Location	Topic	Presenter/Moderator
11:15 A.M. – 12:15 P.M.	Protocol Training Session 4 <ul style="list-style-type: none">- Randomization	<u>Protocol Co-Chair:</u> Adam Czynski
12:15 P.M. – 1:00 P.M.	Lunch	
1:00 P.M. – 3:00 P.M.	Protocol Training Session 5 <ul style="list-style-type: none">- Study intervention- Treatment arms- Rate of weaning- 12 hour window if no wean or escalation by 24 hours- Communication with the pharmacy- Escalation at night/off hours- Rescoring after a feed if scores are high- Non-pharmacologic care- End of intervention- NNS exam	<u>Protocol Co-Chair:</u> Adam Czynski
3:00 P.M. – 3:30 P.M.	Break	
3:30 P.M. – 4:15 P.M.	Protocol Session 6 <ul style="list-style-type: none">- Adverse Events/Serious Adverse Events- Exiting the study intervention- Unmasking	<u>Protocol Chair:</u> Abbot Laptook
4:15 P.M. – 4:45 P.M.	Protocol Session 7 <ul style="list-style-type: none">- Retention- Follow-up points of contacts- 2 year evaluations- Compensation for participant families	Erica Oliveira
4:45 P.M. – 5:00 P.M.	Budget	Meg Crawford
5:00 P.M.	Adjourn	

Tuesday, March 10, 2020

Time/Location	Topic	Presenter/Moderator
7:30 A.M. – 8:30 A.M.	Breakfast	
8:30 A.M. – 9:00 A.M.	Study Monitoring and GCPs	<u>Presenters:</u> Meg Crawford, Terry Lucas
9:00 A.M. – 12:00 P.M.	MOP and Case Reports Form Training <ul style="list-style-type: none">- MOP sections and highlights- Site -level enrollment- Case Report Forms directions and training	<u>Presenters:</u> Abbot Laptook, Adam Czynski, Erica Oliveira
12:00 P.M. – 12:45 P.M.	Lunch	
12:45 P.M. – 1:15 P.M.	Site Activation	<u>Presenters:</u> Shani Alston
1:15 P.M. – 2:15 P.M.	Electronic Data Collection System Electronic Data Collection System directions and training	<u>Presenters:</u> Jenny Auman, James Pickett, Geeta Sunkara
2:15 P.M. – 2:45 P.M.	Final Questions and Wrap-up	
2:45 P.M.	Adjourn	