RFP for EHR Data Collection Center
Application FAQs

August 7, 2018

Q: *"Estimation of staffing and equipment requirements for each site that will contribute data"* - Can you clarify what information the committee seeks for this question? Would you like us to estimate the resources that will be needed at each of the 24 trial sites?

A: If your proposal requires specific resources at the sites, please include a description of what they would be (i.e., equipment, staff effort, etc.).

Q: Does the 5-page limit include budget justification and personnel listing?

A: No

Q: Should we include investigator biosketches?

A: Yes

Q: May we add a separate facilities and resources page (standard NIH format) outside of the 5-page limit?
A: Yes

Q: Should we budget for a 2- or 3-year project period?
A: Budget should be for 2-year project, staffing can be approximate and listed as FTEs.

Q: What is the funding period?

A: We envision the data collection center contract beginning in about January 2019, with enrollment to begin in the trial during the second half of 2019.

Q: What happens if a needed data element is not available at a given hospital?

A: Part of the criteria for selecting hospitals for the trial will be the ability to consistently deliver the key data points. Some data points, however, will be truly missing. These can be reported as missing in the data from the data collection center. PETAL statisticians and investigators will develop a missing data plan (probably multiple imputation for some variables and reported as missing for others).

Q: Is the COROLLA protocol or protocol synopsis available?

A: Protocol summary document has been added to the RFP documents

Q: Is there a provisional list of hospitals that may participate in the trial?

A: The study proposal is for each Clinical Center to identify 2 of their sites (hospitals) to participate. The total number of hospitals for the network will be 24.

Q: How are subjects enrolled in the study: manual screening and consent? auto-enrollment by identification in EHR?

A: The study will be a cluster-randomized design: SpO2 target (low vs intermediate vs high) will be assigned using a cluster-randomized, multiple-crossover design. All participating EDs and ICUs within a study hospital will serve as a unit (cluster); all mechanically ventilated adults in a unit will be assigned to the same SpO2 target at the same time. The SpO2 target will change for each unit at the end of each study period.

Q: Will any data be collected manually?

A: Yes, there will be some manual data collection for the subgroup of patients randomized to the cognitive outcome assessment group.

Q: May we add indirect costs to the budget?

A: Yes