

SINGLE-TRIAL SITE APPLICATION FOR MILRINONE IN CONGENITAL DIAPHRAGMATIC HERNIA TRIAL

RFP NUMBER: NRN-MILRINONE-2021-01

APPLICATION CHECKLIST

Please include this checklist as the cover page to your proposal.

Institution name:	
Address(s):	
Site investigator(s):	
Site investigator email address:	
Site investigator telephone number:	
Business official:	
Business official email address:	
Business official telephone number:	
Submission date:	

Available Population

Please complete the table below detailing the site's available population (if more than one hospital/site is proposed in this application, please provide a separate table for each site).

To be considered for an award, **the offeror must have at least 10 infants per year** that meet the protocol eligibility criteria.

Please provide the most recent 3 year(s) of available data.

Hospital Name:	2018	2019	2020
Number of total NICU beds			
Number of NICU Admissions			
Number of CDH babies admitted ≥ 36 weeks GA at birth or ≥ 2000 g birth weight			
Number of CDH babies treated with ECMO			
Number of CDH babies who survived			

SINGLE-TRIAL SITE PROPOSAL

Below is a preferred protocol template. The descriptions for each section can be deleted to keep the final proposal under the required page limits.

1 GENERAL INFORMATION

Please describe the hospital or institution.

1.1 Site population

Describe your site(s) population demographics and community served relevant to this study's eligibility criteria. Are there any specific local, state, or tribal laws governing human subjects' oversight that would affect participating in this study, and how do you propose to address them?

1.2 Site location(s)

Describe your site(s) location(s), geographic catchment, and any overlap with existing Network sites.

1.3 Current Research at the Site

Please describe any ongoing or upcoming research studies being conducted at the site that may overlap with the proposed study population of infants. If studies exist, please describe recruitment timing/procedures, study implementation procedures, and primary outcomes. How will these studies impact implementation of the Milrinone trial? The Network may need to review the protocols to determine whether they conflict with its study.

2 STAFFING

2.1 Staffing structure

Provide a general description of the site's organizational and supervisory reporting structure for the research staff.

2.2 Experience and ability to provide 24/7 study coverage

Are staff available for study recruitment/implementation coverage for nights, weekends, and holidays (i.e., 24/7)?

2.3 Research staff

List the center research staff, including anyone involved in consenting participants, monitoring and reporting adverse events, data collection, and chart abstraction. Please attach a biosketch of the site PI. Please include short 1-2 sentence biographies of research staff, their degrees/certifications, and their research experience:

- Site PI
- Site coordinator
- Research nurses and assistants

3 SITE FACILITIES AND EQUIPMENT

3.1 Research office space

Is there secure and dedicated research office space? Describe where it is located with respect to the Site PI's office, the Labor and Delivery Unit, and the NICU.

3.2 Investigational pharmacy

Ability to provide 24/7 Investigational Pharmacy/Investigational Drug Service (IDS) coverage. Please give a brief description of the planned process for your site for this trial.

3.3 Follow-up capabilities

Please describe how your team will track participants post-discharge to complete the 4-, 8-, and 12-month postnatal age follow-up phone interviews.

4 STUDY OVERSIGHT AND DATA MANAGEMENT PLAN

4.1 Study oversight

Please describe planned oversight of study procedures and assurance of protocol adherence, especially during the first year by on-site personnel.

4.2 Institutional Review Board(s) (IRBs)

Please describe your institutions oversight mechanism (e.g., IRBs or other committees with oversight) and an estimated timeline for IRB approval.

4.3 Other site oversight requirements

Provide the details construct of non-IRB oversight such as scientific, division, budgetary, nursing, or other review.

What will the training/in-servicing processes be prior to and post-IRB approval?

4.4 Data collection and entry

Provide the plans for data handling (collection, entry, transmission). Data abstraction should be done by qualified medical personnel, particularly for primary and key secondary outcome data. Who will be doing the data abstraction from the medical records?

4.5 Data quality assurance

Please include a detailed description of plans at the proposed site for quality assurance, monitoring data quality. How will accuracy of data entry be assured, and data entry and updates (including screening logs) be tracked? Describe internal methods for data quality control and assurance, as well as strategies for resolution of problems. Describe handling, timing, and resolution of edit corrections, data checks, and audits.

5 STUDY SPECIFIC ISSUES

CDH Registry. Is the site a member of the CDH Registry? If so, for how long?

Pharmacy issues. The protocol spells out details of the milrinone/study drug drip preparation: *“Once the randomization code is received, the study pharmacist at the center will prepare an infusion of milrinone (pre-mixed bags containing 200 µg/mL of milrinone are preferred and do not need any further reconstitution in the pharmacy; Milrinone is also available in 1 mg/mL solution for injection as 10-, 20-, and 50-mL single dose vials).”* Is your pharmacy able to carry out these instructions?

Research-specific tests. The following research specific laboratory and other tests are required for this study on the schedule below. Please describe any special procedures you will need to put into place to conduct these tests in compliance with the protocol, taking into account that the timing of such tests may fall on holidays and/or weekends.

Test	Timing
1 st Cranial ultrasound	Prior to initiation of study drug or within 4 hours of commencement of the study drug
2 nd cranial ultrasound	Within 24 hours (maximum - within 96 hours) of completion of the study drug

APPENDIX 1. BIOSKETCHES OF PERSONNEL

Insert Biosketches.

APPENDIX 2. LETTERS OF SUPPORT

Insert Letters of Support