Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Neonatal Research Network (NRN) Data Sharing Proposal Application

Complete this form to describe your proposed research and request use of existing NICHD NRN data. The text boxes will expand as you type. A complete application includes:

- This completed form.
- Protocol (proposal to analyze NRN data, no longer than 5 pages, excluding tables and graphs)
- A biosketch for the lead author and any co-investigators to be highlighted.
- IRB approval letter for the protocol, if applicable

Once your application is final, it will take approximately 8 weeks for the NRN Data Access Committee (DAC) to provide their recommendation and for the NRN Steering Committee (SC) to make the final decision.

To receive datasets that have not been previously released in public databases, requesting investigators must:

- Provide the necessary funds to reimburse the NRN Data Coordinating Center for its efforts towards producing the requested public use datasets
- Have IRB or Ethics Committee approval or documentation of non-human subjects research determination/ exemption for the proposed study prior to receiving any human subject data.
- Once a request is approved, sign a Data Use Agreement with the NRN Data Coordinating Center. The agreement specifies that the dataset is only to be used for the specific purpose listed in the agreement. The authorized investigator will not copy or distribute it to other people without permission from the NRN Steering Committee. If the recipient moves to a new institution, then a new agreement must be completed.
- Agree to protect subject confidentiality and not seek to, or facilitate mechanisms leading to, the identification of individual subjects who participated in the study.
- The external requestor is asked to acknowledge the use of the NICHD Neonatal Research Network materials in all relevant applications, presentations, and publications, along with a disclaimer that: "The contents of this report represent the views of the authors and do not represent the views of the Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network or the National Institutes of Health." This statement will be placed in the acknowledgement section unless journals request its placement elsewhere in the paper.

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1. Title

2. Authors and Affiliations (including lead author and co-investigators)

Author	Affiliation

3. NRN Study or Studies for which data are requested (consult list of completed NRN studies at https://neonatal.rti.org/index.cfm?fuseaction=home.studies)

4. Background and Rationale

5. Aims and Objectives

6. Short statement of significance of proposed research:

7. Describe analysis plan including sample size and power calculation, type of analyses to be conducted, and draft of tables/graphs when applicable:

8. Who will conduct the analyses?

9. Description of facilities at which the research will be conducted:

10. Estimated start and completion date:

11. Anticipated deadlines (e.g., abstract due dates):

12. Target journals, publications or conferences:

13. Source of funding for this proposal (where applicable):

14. Status of IRB Approval ☐ Attached ☐ Pending ☐ N/A

To Be Completed by Data Coordinating Center:

Additional IRB Required? ☐ **Yes** ☐ **No**

Tracking Number

Date 1st Received

Date Reviewed and Approved by SC*

Date Sent to DAC for Review

Date Revisions Needed Sent to Applicant ☐ N/A

Date Revised Received

Status of Original ☐ Approved ☐ Needs Revision ☐ Not Approved

Status of Revised ☐ Approved ☐ Not Approved

Date of Final Decision by SC

Date Final Decisions Sent to Requestor

Comments:

*** Preliminary SC approval indicates:**

- The proposed study population and requested data are available.
- The proposal does not have significant overlap with proposed or on-going studies by NRN investigators.
- The proposal will not hamper continued participation of study subjects proposed or on-going NRN studies.
- The proposal does not place an undue burden on the DCC.
- The timeline for completion is reasonable
- There are available funds to support the proposed study where applicable.