Vanderbilt-wide Limited Submission Opportunity

NICHD Neonatal Research Network (NRN): Data Coordinating Center (U24 Clinical Trial Optional)

Applications due June 15, 2022

Vanderbilt (VU + VUMC): This is a joint competition for VU and VUMC investigators. All investigators should follow these instructions.

Note that this call is for the Data Coordinating Center (RFA-HD-23-001) ONLY. Please direct any questions about the companion Clinical Center opportunity (RFA-HD-23-002) to LSO@vanderbilt.edu

Overview:

Vanderbilt (VU+VUMC) may submit one application to the NICHD Neonatal Research Network (NRN): Data Coordinating Center (U24) program.

The purpose of the Neonatal Research Network (NRN) is to improve healthcare and outcomes for newborns. This includes finding ways to improve the chances for survival without neurodevelopmental impairment for infants born premature, low-birth weight, or with other serious conditions. NICHD expects the NRN to be its primary and first-line infrastructure involved in implementing multi-site neonatal clinical trials.

The Neonatal Research Network consists of Clinical Centers (CCs) with Neonatal Intensive Care Units (NICUs) and a Data Coordinating Center (DCC). This RFA is specifically for those interested in a Data Coordinating Center application. The DCC’s specific objective is to develop, implement, and analyze results for Network protocols, especially providing biostatistical expertise, computer programming, and project management to design protocols, develop statistical analysis plans, develop data management systems, manage study funds, monitor data integrity and study safety, and work with study investigators to analyze and publish study results.

NIH intends to commit an estimated total of $3,100,000 for the base budget to fund one award, for fiscal year 2023. Future year amounts will depend on funding availability. The maximum project period is 7 years.

Data Coordinating Center (DCC) Responsibilities

- Collaborating with study investigators – both within and outside the Network – in developing Network protocols and budgets for NIH grant submission and/or funding approval.
• Supporting Network protocol design, training, implementation, and study monitoring. The DCC works with study investigators to design protocols, including developing statistical analysis plans, power analyses, and study budgets.
• Coordinating closely with and/or managing the Network sIRB(s).
• Providing data management, including developing protocol manuals and forms, programming data management systems, and preparing reports.
• Conducting statistical analyses of study data and collaborating with study investigators to publish results of Network trials and studies.
• Sponsoring FDA Investigational New Drug (IND) and Investigational Device Exemption (IDE) applications on behalf of the Network.
• Managing study (“capitation”) funds, disbursing payments to CCs and non-Network recruiting sites based on enrolled patients and other study-specific milestone triggers specified in the study protocols and budgets. Working with NICHD Program Staff to develop a detailed financial reporting system.
• Managing Network-wide reporting and data and specimen sharing requirements.
• Providing the logistical support necessary to run an efficient and productive network.

See the solicitation for more information.

**Internal Application Process:**

Anyone interested in being considered as Vanderbilt’s potential nominee must submit the following (in a single PDF) to LSO@vanderbilt.edu by **5 p.m. on June 15, 2022**.

• Brief (2-page maximum) research plan including summary budget
• Proposed list of Vanderbilt key personnel and collaborators
• NIH Biosketch or 5-page CV for each PI/PD
• Statement of support from department chair/center director

Any questions about this opportunity or the LSO process may be directed to LSO@vanderbilt.edu