



The Translating Duke Health (TDH) Children's Health and Discovery Initiative (CHDI) announces a request for research proposals that investigate and positively impact child health and the trajectory of health into adulthood. Preference will be given to projects that involve a new collaboration, build a data resource that will facilitate high-impact child health research, and/or utilize existing data resources at Duke or those developed by the CHDI.

I. Purpose

The intent of this RFP is to support pilot studies that integrate the missions of Translating Duke Health (TDH) and CHDI. Proposals will be chosen to receive funding of up to \$100,000 (direct costs only). The proposed research should be able to be accomplished within one year, and serve as a pilot project for external grant submission. Research groups that submit an external grant application within 18 months of receipt of a CHDI pilot award will receive an additional \$20,000.

We are particularly interested in proposals that would build new collaborations and/or new teams and might lead to extended productive and externally funded collaborations.

Please note that preference will be given to projects that utilize or build unique data resources, or link databases, including:

1. Duke University Health System electronic health records (EHR) data

The CHDI currently has EHR data for all children (<18 years of age) seen at a DUHS provider between January 1, 2014 and December 31, 2017. These data include time resolved patient addresses to allow geocoding of patients over time. We are particularly interested in studies focused on children with suspected/confirmed maltreatment or chronic conditions.

2. Cord blood samples linked to Duke electronic health records

The CHDI has linked Carolinas Cord Blood Bank donors who were born at Duke to long-term Duke electronic health records (1998-2017). EHR data elements include diagnoses, health care encounters, vitals, problem lists, and demographics. All patient identifiers have been removed. There are approximately 4400 individuals within this dataset. Sample availability will be determined on a case-by-case basis in consultation with Dr. Joanne Kurtzberg, Director of the Carolinas Cord Blood Bank.

3. Project HOPE 1000 data and/or samples

Project HOPE 1000 is a longitudinal observational study of mother-infant dyads, with data and samples collected from the first trimester of pregnancy through the infant's second birthday. All participants must receive healthcare through Duke University Health System and are consented for access to electronic health records, social services, and educational data. Biospecimens collected as part of the protocol include peripheral blood; urine; vaginal, rectal, oral, and nasal microbiome; placenta; and cord blood. Participants complete surveys related to social determinants of health, diet, and environmental exposures.

4. Environmental data

The CHDI has assembled a temporally and spatially resolved database of air quality, climate, and built environmental data that can be linked to other data sources.

5. We are also interested in working with investigators who wish to leverage administrative data from local, state, or national entities (birth records, Medicaid claims data, court data, etc.); patient/disease registry data; or research data models (PCORnet, Pedsnet). While CHDI cannot provide direct access to these resources, members of the CHDI leadership team can provide guidance/assistance in accessing these types of data.

A meeting with CHDI leadership is required if you would like to use these resources. Please contact [Jillian Hurst](#) if you would like to discuss the use of these resources in your proposal. All teams wishing to use a CHDI resource must arrange a meeting by July 1, 2019.

Proposals should describe:

- A research question centered on early life influences in health and disease
- The study population of interest
- Data required to answer the research question
- Unique data resources that will be used or built by the study
- A plan for statistical/data science support, including collaborators
(CHDI can provide statistical support if a proposal does not identify a specific collaborator. Any applicant requiring statistical support must contact CHDI (childrensdiscovery@dm.duke.edu) no later than 4 weeks prior to the submission deadline in order to arrange a consultation with a CHDI-affiliated biostatistician)
- A plan for follow-on funding applications

We plan to award up to four grants, each with a total budget of up to \$100,000 (direct costs only) and a project duration of 1-2 years, based on the following criteria:

- Overall impact
- Significance & Innovation
- Approach
- Feasibility
- Potential for future funding –The proposed pilot work should collect preliminary data or develop tools that will lead to a competitive proposal submitted to an external funding agency. All proposals must specify how data and/or resources generated by the pilot study will contribute to submission of a grant application, including specific funding opportunities.

Proposals should be organized as follows:

- Title (80 characters max)
- Name and contact information for Project Leaders
- Project Abstract (250 words max)
- Project summary in 4 pages or less (11 point Arial font, half-inch margins, inclusive of figures but not including citations), addressing the selection criteria listed above.

Additional documents (uploaded separately from the research proposal):

- Rationale for CHDI support – How does this research advance the mission of CHDI? (1/2 page max)
- Plans for external grant submission (1 page max)

- Budget and budget justification using PHS 398 Form Pages 4 and 5 (Page 5 is for the Budget Justification section only and you may use more pages as needed. Combine all pages into a single PDF with no page limit).
- Proposal timeline (1 page max)

II. Details

- Application Submission Deadline: **September 10, 2019**.
- Proposals should not exceed four single-spaced (11-pt type) pages. Please also include a current NIH-style biosketch for all PIs.
- Funding: Each award will consist of up to \$100,000 (direct costs only) with an expected start date of **November 1, 2019** and ending on **October 30, 2020**.

II. Proposal Preparation

Email indication of Intent to Apply addressed to [Jillian Hurst](#). Required consultation with members of the CHDI to determine whether the proposed project can be accomplished using the available CHDI resources (**request must be received by July 1, 2019**).

III. Selection Process and Review Criteria

1. Application Submission: A Review Committee comprised of researchers from CHDI will perform a detailed review of the applications. The Review Committee will consider the following criteria when reviewing applications and assigning an overall score:
 - Overall impact
 - Significance
 - Investigators
 - Innovation
 - Approach
 - Environment
2. Fulfills missions of CHDI
3. Potential for future funding: The proposed pilot work should collect preliminary data or develop tools that will lead to a competitive proposal submitted to an external funding agency. All proposals must specify how data and/or resources generated by the pilot study will contribute to submission of a grant application, including specific funding opportunities that the Project Leaders plan to pursue.
4. Funds will be released when all IRB, animal use, and institutional approvals are obtained (as applicable).

IV. Application Procedure

CHDI uses the MyResearchProposal online application software to submit applications.

- To apply visit <http://bit.ly/myresearchproposal>, click on “Create New User” (or log in if you already have an account). Proposals must be submitted to the system by only one of the Principal Investigators.
- A step-by-step user’s guide for applying via the MyResearchProposal software is available - Please review the guide [here](#).
- Enter Access Code “**CHDI**” and follow the instructions.

Proposal sections (except the Abstract and Public Summary) will be uploaded as individual PDF files. The application sections are:

- Abstract: The abstract is a summary of the proposal for use by review committee members and CHDI (250 words maximum. Please include a brief introduction, the aims, and the expected outcomes).
- Research Proposal (4-page limit, including tables and figures. Use 1-inch margins, single line spacing, and font no smaller than Arial 11. References do not count towards the 4-page limit.) The research proposal should address the following:
 - Specific Aims/Project Goals (1-page)
 - Significance
 - Innovation
 - Approach
 - Impact
 - References (please note that references do not count towards the 4-page limit and should be included at the end of the research proposal PDF)
- Rationale for CHDI support – How does this research advance the mission of CHDI? (1/2 page max)
- Future directions and plans for external grant submission (1 page max)
- Budget with Budget Justification using [PHS 398 Form Pages 4 and 5](#) (Page 5 is for the Budget Justification section only and you may use more pages as needed. Combine all pages into a single PDF with no page limit). **Please note that you must provide a separate budget for the additional \$20,000 awarded upon submission of an external grant application.**
- Proposal timeline detailing the project milestones and deliverables (1 page max)
- Human and/or Animal Subjects: Institutional Review Board (IRB) or Institutional Animal Care & Use Committee (IACUC) approval **is not required prior to submission but will be required prior to funding.** Briefly describe any human and/or animal subject issues. (For example, if human subjects are involved, provide a description of their involvement and characteristics. Describe the sources of materials that will be obtained from human subjects as part of their study participation. Provide assurance that the project will be reviewed and approved by the Duke IRB and comply with HIPAA. If vertebrate animals are to be used, provide a description of the proposed use of the animals in the work. Projects involving animal subjects must be reviewed and approved by the Duke IACUC. There is no page limit to this section, but it should be as brief as possible.)
- NIH Biosketches for key members of the research team (as a single PDF).

V. Budget Guidelines

Please note the following during budget preparation:

1. No indirect or overhead costs may be included; the awardees receive direct costs only.
2. All funds are subject to G&A of 15% - this should be included in the budget.
3. **Provide a separate budget for the additional \$20,000 awarded upon acceptance of an external grant application.**

4. Grant funds may be budgeted for

- salary support for students (including prorated tuition remission), post-docs and research support personnel. (Salary for research staff and students must reflect actual institutional based rates supplied to you by your grants managers or business office.)
- travel necessary to perform the research
- small equipment, subcontracts, research supplies and core lab costs, or
- other purposes deemed necessary for the successful execution of the proposed project

5. Grant funds may **not** be included in the budget

- salary support for the PI or faculty collaborators
- foreign components, as defined in the NIH Grants Policy Statement
- effort for post-doctoral trainees or fellows that are already on training grant equivalents
- capital equipment
- office supplies or communication costs, including printing
- meals or travel, including to conferences, except as required to collect data
- professional education or training
- computers or audiovisual equipment
- manuscript preparation and submission, or
- indirect costs (The indirect rate is 0% for all direct costs, including subcontracts. You and/or your grants manager will be responsible for working directly with your subcontractor to obtain a final budget to include with your final budget.)

Awarded funds must be used to conduct the proposed research. CHDI reserves the right to revoke funding in the event it is determined that funds were not spent in accordance with the approved proposal without prior notification and approval.

VI. Terms of the Award

A. Approvals Required Prior to Funding Start Date

Prior to receiving funds, research involving human subjects must have appropriate approvals from the Duke IRB. If the research includes animals, the appropriate IACUC animal research forms must also be approved before the project's start date. Failure to pursue approval and notify CHDI of the outcome in the requested timeframe may result in cancellation of funding.

B. Project Execution

Investigators agree to submit a brief interim report (6-months after project start), a brief report at the end of the funding period, and a detailed written report 12 months after the conclusion of the funding period that includes applications for or acquisition of additional funding, submitted or published manuscripts, presentations, invention disclosures, and other outcomes. CHDI may terminate and reallocate residual

funds for any team failing to submit required written reports in a timely manner. Proposed aims of funded projects may be changed, added, or deleted during the funding period, pending Investigator and CHDI review and agreement. Projects must complete in the 12-month period; no-cost extensions are not permitted.

Investigators will meet with CHDI before release of funds to review project plans and ensure projects are ready to start by **November 1**.

C. Post-Award Reporting

CHDI tracks significant events resulting from the funding. Any significant events should be included in the final project report, and CHDI will contact investigators annually to determine if any significant events have been achieved as a result of this award. Examples include:

- Abstracts/presentations, manuscripts, published guidelines
- Additional funding
- Regulatory meetings and filings
- Initiation of clinical studies
- Improved diagnosis or treatment of disease
- Implementation in clinical practice and community
- Translation of models to other geographical areas
- Translation of models to other therapeutic areas
- Clinical outcomes in practice and communities
- Agreements with partners and strategic collaborators to translate the research
- Commercialization (e.g. new intellectual property, license, commercial partnerships, or start-up company)
- Direct-to-consumer interactions (e.g. apps)

When requested, all awardees will be expected to provide updates of publications and other successes that originated from the award.