Childress Institute for Pediatric Trauma (CIPT) Request for Applications for Pilot Awards

Overview

Life-threatening injury is the No. 1 killer of children in the US. Nearly 10,000 children lose their lives every year from serious injuries. In addition, almost 300,000 children are hospitalized and over 8 million children are treated in the emergency department for serious injuries each year, many of whom struggle with long-term recoveries and disabilities. Injuries can happen anywhere, at any time, to any child. The mission of the Childress Institute for Pediatric Trauma (CIPT) is to discover and share the best ways to prevent treat serious injuries children.

Purpose

The CIPT is seeking proposals for projects that support our goal to eliminate death and disability to injured children. Existing or newly formed inter-disciplinary teams are encouraged to submit proposals. Preliminary/pilot data are not required. Research should address important questions about pediatric injury (≤18 years old) that can be integrated into any aspect of the care continuum from prevention of acute injury through rehabilitation and recovery. Pilots in this cycle should align with institutional key strategic areas of: 1) clinical preeminence and synergy, 2) social impact and health equity, 3) innovation and partnership, and 4) growth, integrated scale and influence. Projects are encouraged to leverage resources provided by the CTSI and other CTSI supported centers.

Funded proposals will receive up to $50,000 total, to be spent within a 12-month project period.

Eligibility

This award is open to investigators with faculty rank across the Southeast region of Advocate Health, which includes Atrium Health, Atrium Health Navicent, and Atrium Health Wake Forest Baptist, including Wake Forest University School of Medicine. New and early-stage investigators and/or proposals collaborating with partners within the Atrium Health Network are especially encouraged. Basic science and/or animal model clinical-translational projects are not eligible.

The application must include:

- A Principal Investigator that is a faculty member (Instructor and above)
- A plan for actionable use of pilot data for publication and/or future grant application(s)
- A clear statement of the how the project addresses a problem or critical barrier in pediatric injury and supports the mission of the CIPT

Key Dates

Date	Detail
11/01/2024, 11:59 pm EST	Letter of Intent (LOI) Deadline
12/02/2024	Investigators Invited for Full Application
12/09/2024 – 12/20/2024	Virtual research studio for Investigators
02/28/2025 11:59 pm EST	Full Applications Deadline
04/01/2025	Selection of Awardees
05/01/2025	Project Start Date
04/30/2026	Project End Date

Funding

The CIPT will fund up to $50,000 in direct costs. See section on Budget Guidelines for more details on allowable and non-allowable budget items.

Application Procedure

Letter of Intent Deadline: 11/01/2024, 11:59 pm
Letters of Intent (LOI) (2 pages max) require the following:

- A brief abstract, including specific aims.
- A clear statement of how the project will address significant questions in the prevention and/or treatment of pediatric injury. Study methods and feasibility of projects should also be included.
- A list of study team members for the proposed project. All team members should have agreed to participate in the project.

The LOI should be submitted through the ePilot electronic submission system by the LOI deadline noted above. Substantive questions about your proposed research project should be directed to Dr. Barbara Yoza at byoza@wakehealth.edu. Questions about the ePilot electronic submission system should be directed to Katelyn Still at kastill@wakehealth.edu

Review Criteria and Process for Letters of Intent

- Administrative review will assure that project is responsive to RFA and that LOI adheres to submission guidelines.
- LOI review by the CIPT steering committee will assess the study's potential impact preventing/treating pediatric injury and whether study's feasibility/methods are likely to achieve actionable results.
- Selection of investigators invited to submit a full application will be communicated via e-mail on 12/02/2024.

Investigator(s) Virtual Research Studio:

- Research Studios will be scheduled for up to 1H sometime between 12/9/2024 – 12/20/2024
- Selected applicants and their collaborators will be asked to give a timed presentation limited to 15 minutes of their research idea(s), followed by up to 45 minutes of active conversation with experienced investigators/researchers and clinical leaders selected by the CIPT. This is an opportunity for applicants to further develop and/or refine their proposed research project in discussion with content experts.
- Experts will also provide feedback to the CIPT on the project's feasibility, innovation and potential impact on pediatric injury.

Format Specifications

- Visual and oral presentation through a virtual platform; LOI will be reviewed by experts before the research studio
- Timed PI presentation with a maximum of 15 minutes; project discussion maximum of 45 minutes

Full Application Deadline: 02/28/25, 11:59 pm
Investigators invited to apply will receive an e-mail on 12/02/2024 with a link to the ePilot electronic submission system for submitting a full application. Full application instructions are summarized below.

Format Specifications

- Arial font and no smaller than 11 point
- Margins at least 0.5 inches (sides, top and bottom)
- Single-spaced lines
- Consecutively numbered pages

Submission/Applicant Information (submission system form)

- Project Title
- Name and institutional affiliation of PI, Co-Investigator(s), and other Key Personnel

Abstract (submission system form) (300 words max)

Lay Summary (submission system form) (300 words max)

Key Words (submission system form) (not to exceed 6)

Research Plan (upload Word document or PDF; maximum 5 pages organized as follows)

- *Specific Aims (1 page maximum)*
- *Research strategy (in the order specified)*
  - *Significance* – Explain the importance of the problem or critical barrier in pediatric trauma that the project seeks to resolve.
  - *Innovation* - Describe any novel concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and explain how the project challenges and improves clinical practice paradigms.
  - *Approach* -
    - Describe the overall strategy, methodology, and analyses to be used to accomplish each aim. Include how the data will be collected, analyzed (including power calculation and statistics), and interpreted as well as any resource sharing plans as appropriate.
    - If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.
    - Discuss anticipated outcomes, including predicted results and plans for actionable use of pilot data for publication, future grant application(s) and/or dissemination of project results to the pediatric trauma care community. Include a discussion of potential problems, alternative strategies, and milestones anticipated to achieve each aim.
- *Investigators* – Describe the contribution of each team member to the project and how their expertise and experience supports project success. A leadership and team communication plan should be included.
- *Projected Timeline* – Provide 12-month timeline for project milestones.

References (no page limit)

Information Regarding Human Subjects

Address the following if the project **involves human subjects**.

- Provide a one-page document addressing the Protection of Human Subjects, if applicable.
- IRB Approval Status – IRB protocols must be approved prior to funding of the approved pilot. IRB approval is not required for full application submission, however **a delay in IRB approval does not alter the project end date.** Pre-submission discussion with the Wake Forest IRB is strongly suggested.
- Data and Safety Monitoring Plan (DSMP) and (DSMB), if applicable. If you are unsure how much safety monitoring your study will need, please contact the IRB/HRPP Director, Brian Moore at jbmoore@wakehealth.edu.

Budget and Justification (budget template plus 1-page justification)

- Complete the budget template form provided along with a brief justification for the funds requested for this RFA. Please include explanation of other resources that may be leveraged to support the project.

NIH biographical sketch for all Key Personnel (FORMS-H)

Other Support Information for all Key Personnel

Budget Guidelines

The budget period is for 12 months ending no later than 04/30/2026. Up to $50,000 in direct costs may be requested.

Grant funds may be budgeted for:

- Research support personnel (including undergraduate and post-graduate students)

- Research faculty effort directly related to pilot work up to a maximum of 20% of the total budget, not to exceed $10,000 for salary and fringe; calculations utilize the current NIH cap maximum salary of $221,900
- Consultant honoraria for external (non- Advocate Health Network) collaborator(s) up to $1,000 total per budget
- Travel necessary to perform the research; travel to conferences and/or per diem not allowable
- Small equipment, research supplies and core lab costs
- Other purposes deemed necessary for the successful execution of the proposed project
- Grant funds may **not** be budgeted for:
    - Office supplies or communication costs, including printing
    - Professional education or training
    - Computers or audiovisual equipment, unless fully justified as a need for the research
    - Manuscript preparation and submission
    - Indirect costs

Awarded funds must be used to conduct the work proposed. All direct charges to this award must adhere to federal regulations and requirements regarding the use of CIPT endowment funds. The CIPT reserves the right to revoke funding in the event it is determined that funds are not used in accordance with the approved protocol. The general criteria for determining allowable direct costs on federally sponsored projects is set forth in 2 CFR Part 200: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (The Uniform Guidance).

Review Criteria and Process

CIPT proposals are competitive and peer-reviewed. Proposals will be evaluated by CIPT Pilot Fund Committee members and based on NIH review criteria and scoring. Final award approval will be at the recommendation of CIPT leadership.

Funding decisions will be made based on the reviews of an evaluation of the projects' connection with the goals of the CIPT. IRB protocols must be approved prior to funding of the approved pilot

Reviewers will score applications from 1 to 9 based on:

- The significance of the proposed research to pediatric trauma
- Qualification(s) of investigator(s) and strength of leadership plan
- Innovation of the approach and feasibility
- Methodological rigor with clear milestones
- Likelihood that project results will inform/improve/innovate clinical practice paradigms in pediatric trauma
- Actionable use of pilot data regardless of whether the study yields positive or negative results
- Other elements to be considered in the review include: the likelihood that the investment will lead to external funding or a licensable innovation, early-career faculty involvement, and the proposal should follow the core values and CultureVision™ of the Advocate Health Network.

Program Expectations

If any significant issues arise, the study team will be required to work with CIPT leadership to define an intervention strategy for the study to be successfully completed (or in rare cases, terminated).

Specific Deliverables Include:

- Membership in the CIPT
- Provide a written quarterly progress reports and a final report (project and financial) within 60 days of project completion
- Presentation of project results at a CIPT leadership meeting
- Participation in CIPT development activities as requested

- Disclosure of implementation/dissemination results and efforts to seek extramural funding beyond the pilot grant and subsequent notification of any funds obtained and/or related publications or significant collaborations from the project for a minimum of 4 years.

Other Guidelines

1. Prior to receiving funds, research involving human subjects must have appropriate approvals from the IRB. Either an IRB approval letter or an IRB response to a "Determination Whether Research or Similar Activities Require IRB Approval" must be submitted to the CIPT prior to funds being released. Human subjects must be reviewed in accordance with the institution's general assurances and HIPAA. All key personnel must have certification of training in the protection of human subjects prior to the start of the grant period. Clinical trials must be registered at ClinicalTrials.gov.
2. It is expected that the PI reports any outcomes due to the pilot award, e.g., subsequent external funding, publications, presentations and patents.
3. All publications that are the direct result of this funding must reference: "Research reported in this publication was supported by the Childress Institute for Pediatric Trauma, Wake Forest School of Medicine." Publications must also be registered in PubMed Central.
4. Any awardee/team member who leaves their position should contact the CIPT to discuss future plans for the project.

Grant Administration

The PI is responsible for the administration and final account reporting of grant funds. Projects will be for a 12-month period of time.

Contacts

Substantive questions about your proposed research project should be directed to Dr. Barbara Yoza at byoza@wakehealth.edu

Questions about the ePilot electronic submission system should be directed to Katelyn Still at kastill@wakehealth.edu