



**Digestive Health Center (DHC):
Bench to Bedside Research in Pediatric Digestive Disease**

\$50,000 Pilot & Feasibility Funding Opportunity
Due: December 7, 2015 at 5:00 pm

Jorge A. Bezerra, MD
Director

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Program Manager

Applications are solicited for pilot projects to conduct basic, translational, patient based or outcomes research broadly relating to pediatric digestive disease. Applications will be considered in all areas of digestive disease research with particular emphasis on the following Digestive Health Center research themes:

Chronic Liver Disease
Inflammatory and Diarrheal Diseases
Obesity and the Digestive System
Development and Digestive Diseases

Funds will support highly focused projects from individual investigators with the goal of generating preliminary data sufficient to support an application for independent research through traditional NIH mechanisms. Funding for projects will range from **\$40,000 to \$50,000** depending on budgetary needs and number of selected applications.

The deadline for submission is **Monday December 7, 2015 at 5:00 pm**. Send a single PDF file of the assembled application to cynthia.wetzel@cchmc.org.

Questions should be sent to either:

Aaron Zorn, PhD (DHC P/F Program Director) aaron.zorn@cchmc.org

Cynthia Wetzel, PhD (DHC program manager) cynthia.wetzel@cchmc.org.

See application guidelines and eligibility on the following pages.

Digestive Health Center (DHC) Pilot and Feasibility Application Guidelines

Overview

Pilot and feasibility (P/F) applications are solicited for pilot projects to conduct basic, translational, patient based or outcomes research broadly relating to pediatric digestive disease. Applications will be considered in all areas of digestive disease research with particular emphasis on the following Digestive Health Center research themes: Chronic Liver Disease, Inflammatory & Diarrheal Diseases, Obesity & the Digestive System, and Development & Digestive Diseases. Applications should be focused proposals with aims that can be clearly accomplished within 1-2 years. The extent to which Research Core laboratories of the DHC are utilized should be emphasized in the proposal. Visit the DHC web site by clicking [here](#) for descriptions of the core services offered. Successful applicants will have the same core access priority for these projects whether or not the applicant is a DHC member.

Eligibility

Applicants must have a faculty appointment at Cincinnati Children's Hospital Medical Center and/or the University of Cincinnati by July 1, 2016.

Current membership in the DHC is not required.

The following are eligible to apply. These descriptions are used to identify the type of application.

- 1) **New Investigators:** Investigators without current or past NIH support at the R01 level. K08, K01, and K23 recipients are eligible. Recipients of NRSA (F32) or T32 awards are also eligible if they are in their final year of funding*.
- 2) **New Digestive Disease Investigators:** Established, NIH-funded investigators with no previous work in digestive diseases who wish to test the applicability of their expertise to a digestive-disease related problem.
- 3) **Established Digestive Diseases Investigators:** Investigators who wish to test the feasibility of an innovative idea, which constitutes a significant departure from their funded work.

For Multi-PI projects the type of application (1-3) is based on the most senior PI.

**Trainees in their last year of fellowship, including NRSA individual awardees (F32) or institutional training grant (T32) recipients are eligible for P/F funds if they have had at least two years of research experience at the start date of the P/F project, and have suitable expertise and independence to carry out the planned experiments. Trainee applicants must include a letter from their mentor that states the applicant's scientific independence and an institutional commitment of a faculty position as of July 1, 2015. Applicants who have completed training within one year and remain affiliated with their mentor must have a letter stating how this project is separate from the mentor's work.*

2nd Year of Funding Process

P/F Grant Awardees are eligible to apply for a second year of funding. The format of the application and the submission process are the same as for all DHC P/F grant applications (see below). In the "Research Plan," you will need to clearly describe: 1) the progress toward the original aims during the first year of funding, 2) how the work proposed for the second year relates to the original aims, 3) publication(s) and outcome of extramural grant applications related to the first year of funding.

Format

The applications must contain the following[#], in order (See Word file for forms):

[#]All forms are modified from current NIH forms with the goal to facilitate future preparation of NIH grant applications.

1. Face page
2. Project summary, relevance, division or institute, & personnel
3. Table of Contents
4. Detailed budget and budget justification.
 - Salary support is allowed for anyone working on the project other than the principal investigator. Principal Investigator salary support is not permitted.
 - Pilot and Feasibility Projects should utilize DHC Research Core laboratories. Specific plans to use the cores on a fee-for-service basis should be included in the budget, where applicable.
 - The budget should include direct costs up to \$50,000 and appropriate indirect costs.
5. NIH Biosketch **for PI and Co-Investigators (if appropriate).**
6. Other Support: **Provide other support for ONLY the principal investigator.** Especially include sources of funds currently available to support research that is described in this application or closely related topics. If any overlap exists between this application and any other currently funded, or pending projects, clearly indicate why DHC Pilot and Feasibility Program funds are being requested. Duplication of funds is not permitted.
7. Body of Application- **5-page limit based on NIH format**
 - a. **Specific Aims (1/2 page):** Remember this is a 1-2 year pilot project.
 - b. **Research Strategy (4 ½ pages).** Organize the Research Strategy into three sections - *Significance*, *Innovation* and *Approach* using the instructions provided below. Include a thorough, but concise description of the work leading up to your current hypothesis (applicants are not required to have extensive preliminary data since this is a pilot project).
 - **Significance:** Explain how the proposal will address an important problem or a critical barrier in the field. Also indicate how this proposal will generate significant preliminary data needed for an NIH grant application.
 - **Innovation:** Explain how the proposal challenges existing paradigms or clinical practice; address an innovative hypothesis or critical barrier in the field.
 - **Approach:** Describe the overall strategy, methodology, and planned statistical analyses used to accomplish the specific aims of the project. Include preliminary data, a rationale for experimental design and discuss any potential problems and solutions.
8. Human Subjects. Include all required sections required for NIH application. [See PHS 398 instructions](#)
9. Vertebrate Animals. Include 5 point narrative required for NIH application. [See PHS 398 instructions](#)
10. Literature cited. Provide full details of literature cited including full title and authors.

11. Brief description of long-term goals of the research project the applicant plans to develop. What are the plans for future funding if the line of investigation is successful? Describe how the project is related to one of the themes of the DHC:
 - a) [Chronic Liver Disease](#)
 - b) [Inflammatory & Diarrheal Diseases](#)
 - c) [Obesity & Digestive System](#)
 - d) [Development & Digestive Diseases](#)
12. Brief description of the proposed use of DHC Research Cores (if any). Click on the links for descriptions of the core services:
 - a) [Gene and Protein Expression Core](#)
 - b) [Bioinformatics Core](#)
 - c) [Integrative Morphology Core](#)
 - d) [Pluripotent Stem Cell and Organoid Core](#)
 - e) [Clinical Component- Data Analysis and Management](#)
13. Letter of support from your Division Director stating availability of resources and time commitment.
14. Letters of support from consultants if any.
15. Appendix materials.
16. Supplementary data will **NOT** be accepted.

Review Process

Applications will be evaluated and scored by at least two members of the DHC "Study Section" review panel. The selection process will consist of 2 steps: 1) Identify approximately 6 applications based on their scores from the review panel and 2) Brief presentation of the research plan by individual applicants to the DHC External Advisory Board (EAB). The EAB will make a recommendation regarding the final selection of those applicants that will receive funding. Members of the review panels will follow strict conflict of interest guidelines.

The main criteria for the review of the application are:

- Scientific merit of the application.
- Type of application (1-3) as described above.
- Is the proposed work likely to position the applicant to a highly competitive NIH application?
- Is the proposal related to one of the focus areas of the DHC: a) chronic liver disease, b) digestive organ failure, development and transplantation, c) inflammatory and diarrheal diseases, or d) obesity?

It is strongly recommended that investigators planning to submit an application have a consultation with the DHC Data Analysis and Management Core for statistical analysis prior to submission. To obtain a consultation, complete the form at the [CCTST website](#). Please include in the consultation request that you are submitting a DHC Pilot and Feasibility Application and make sure you indicate the project is affiliated with the "Digestive Health Center" in the drop down menu on the form.

Applications that are recommended for presentation to the EAB will be reviewed by the DHC Data Analysis and Management Core for statistical methods and implementation. Approval from the core will be required before funding starts.

For questions contact Eileen King, PhD; Phone: 803-1819; email: eileen.king@cchmc.org