



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

\$50,000 Pilot & Feasibility Funding Opportunity
Due: December 7, 2009 at 5:00 pm

Applications are solicited for pilot projects to conduct basic, translational, and 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:

Jorge A. Bezerra, MD
Director

Mitchell B. Cohen, MD
Associate Director

Lee A. Denson, MD
Associate Director

Aaron M. Zorn, PhD
Associate Director

Cynthia C. Wetzel, PhD
Program Manager

Chronic Liver Disease
Digestive Organ Failure and Transplantation
Inflammatory and Diarrheal Diseases
Obesity

Funds will support highly focused projects from individual investigators and are intended to provide support to collect 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. Eligible applicants must have a faculty appointment at Cincinnati Children's Hospital Medical Center (CCHMC) and/or the University of Cincinnati College of Medicine by 7/1/10. Current membership in the DHC is not required.

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

- 1) Investigators without current or past NIH support at the R01 level. K08 and K23 recipients, as well as recipients of NRSA (F32) or T32 awards are eligible if they are in their final year of funding. These applicants are considered new digestive disease investigators.
- 2) Established, funded investigators with no previous work in digestive diseases who wish to test the applicability of their expertise to a digestive-disease related problem. These applicants are considered new digestive disease investigators.
- 3) Established investigators in digestive diseases who wish to test the feasibility of an innovative idea, which constitutes a significant departure from their funded work and/or established investigators forming new collaborations.

Application Guidelines

Overview

Pilot and feasibility (P/F) applications should be focused proposals, the aims of which can be clearly accomplished within one to two years. The extent to which Research Core laboratories of the DHC are utilized should be emphasized in the proposal. See the DHC web site www.cincinnatichildrens.org/dhc 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 member of the DHC.

Review Process

Funding is limited to one year support at a maximum level of \$50,000. Applications will be evaluated and scored by the DHC "Study Section." The selection process will consist of two steps. The first step will identify approximately 6 applications based on their scores. The second step will consist of a 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.

2nd Year of Funding Process

As a recipient of a P/F Grant Award, you are eligible for a second year of funding. You will need to submit a revised grant application during one of the annual requests for applications for DHC P/F Project proposals (usually in the Fall). 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

There is a **5-page** limit for the body of the application (Hypothesis and Specific Aims, Background/Significance, Preliminary Studies, Research Design and Methods).

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

1. Modified NIH face page (PHS 398 Face Page)
2. Modified NIH project summary, relevance, performance site & personnel (PHS 398 Form Page 2)
3. Modified Research Grant Table of Contents (PHS 398 Form Page 3)
4. Modified detailed budget for the entire proposed period of study and budget justification. Pilot and Feasibility Program 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. (PHS 398 Form Page 4 & 5)
5. NIH Biosketch indicating research projects ongoing or completed during the last 3 years. (Not to exceed 4 pages.)
6. Other Support: Provide other support for ONLY the principal investigator, especially sources of funds currently available to support research on this or closely related topics by the applicant. If funds exist, clearly indicate why DHC Pilot and Feasibility Program funds are being requested. Duplication of funds is not permitted.

7. Resources
8. Body of Application- **5-page limit (below lists approximate length for each section)**
 - a. Specific Aims (1/2 page: Remember this is a 1-2 year pilot project).
 - b. Background and Significance (1-2 pages: Include a thorough, but concise description of the work leading to your current hypothesis and a review of the literature).
 - c. Preliminary studies (1 page: You are not required to have preliminary data since this is a pilot project. Briefly describe relevant preliminary work that you have done supporting this application.)
 - d. Research Design and Methods (1-3 pages of study design, methodology, data analysis, any problems anticipated and potential solutions. Include rationale for experimental design and reasons for favoring one methodology over another. Describe how you will analyze data; identify potential problems and solutions.
9. Human Subjects – See PHS 398 instructions.
10. Vertebrate Animals – See PHS 398 instructions.
11. Literature cited. Provide full details of literature cited including full title and authors.
12. Brief description of long-term goals of the research project you plan to develop. Include rationale for the planned research program based on past experience of the applicant. 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. Digestive Organ Failure and Transplantation
 - c. Inflammatory and Diarrheal Disease
 - d. Obesity
13. Brief description of the use of DHC Research Cores (if any)
 - a. Gene Expression and Sequencing Core
 - b. Bioinformatics Core
 - c. Integrative Morphology Core
 - d. Clinical Component- Biostatistical Service
14. Brief description of the consultation with the Biostatistical Service. Each applicant **MUST** have a consultation with one of the staff members of the Biostatistical Service. To obtain assistance you need to complete the request form by going to the “Research Central” tab at the CCTSA website: <http://cctst.uc.edu/>. Please inform the staff you are submitting a Digestive Health Center Pilot and Feasibility Application. For questions contact Christopher Lindsell, PhD; Phone: 558-6937; email: biometrcs@cchmc.org
15. Letter of support from your Division Chief stating availability of resources and time commitment.
16. Letters of support from consultants if any.
17. Appendix materials.
18. Trainees in their last year of fellowship, including those who are recipients of an NRSA individual award (F32) or an institutional training grant (T32) 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 have a letter of commitment from a senior scientist to sponsor the project and an institutional commitment to a faculty position.

19. Applicants who have completed training within one year and remain affiliated with a mentor must have a letter stating how this project is separate from the mentor's work.
20. Supplementary data will **NOT** be accepted.

The main criteria for the review of the application are:

- Scientific merit of the application.
- Type of application: From 1 to 3 (as above).
- Is the proposed work likely to position the applicant to a highly competitive NIH application?
- Relatedness to disease-oriented research:
 1. 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?
 2. Does the proposal contain pre-clinical or patient-based studies?

Submission guidelines and forms are available on the Digestive Health Center (DHC) web site: www.cincinnatichildrens.org/dhc.

The deadline for submission is **Monday December 7, 2009 at 5:00 pm**. Applications should be sent to **Cynthia Wetzel, PhD** (Program Manager DHC) at cynthia.wetzel@cchmc.org.

Questions should be sent to either **Aaron Zorn, PhD** (DHC Pilot and Feasibility Program Director) at aaron.zorn@cchmc.org or **Cynthia Wetzel, PhD** (Program Manager DHC).