



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

\$50,000 Pilot & Feasibility Funding Opportunity
Due: Monday November 25, 2024 at 5:00 pm

Lee A. Denson, MD
Director

Theresa Alenghat VMD, PhD
Associate Director

Alexander G. Miethke, MD
Associate Director

Nicholas J. Ollberding, PhD
Associate Director

Cynthia C. Wetzel, PhD
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 [DHC research themes](#):

Mechanisms of Liver Disease
Digestive Disease and Immunity
Stem Cell and Organoid Modeling of Digestive Disease

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 National Institutes of Health (NIH) mechanisms. Funding for projects will range from **\$40,000 to \$50,000** depending on budgetary needs and number of selected applications.

Submission deadline is **Monday November 25, 2024 at 5:00 pm**. Send a **single PDF file** of the assembled application to cynthia.wetzel@cchmc.org.

Questions should be sent to either:

Theresa Alenghat, VMD, PhD (DHC P/F Program Director)
theresa.alenghat@cchmc.org

Cynthia Wetzel, PhD (DHC 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: Liver Disease and Modeling, Digestive System and Immunity, Digestive System and Obesity, and Translational Embryology. Applications should be focused proposals with aims that can be clearly accomplished within 1-2 years. A description of the proposed [DHC supported Research Cores](#) that will be utilized should be included in the application. 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 **full-time** faculty appointment at the Instructor level or higher at Cincinnati Children's Hospital Medical Center and/or the University of Cincinnati by July 1, 2025.

Current membership in the DHC is not required.

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

- **New Investigator (N):** Investigators without current or past NIH support at the R01 level. K08, K01, and K23 recipients are eligible and are encouraged to apply. Recipients of NRSA (F32) or T32 awards are also eligible if they are in their final year of funding*.
- **Established Investigator, New To Digestive Diseases Research Field (NTF):** Established Investigators from other areas of biomedical research to use their expertise for digestive diseases research.
- **Established Digestive Disease Investigator (E): NEW CATEGORY THIS YEAR** Established digestive disease researcher who previously had R01 level funding but does not currently have R01 or R01-level equivalent funding as a PI or Multi PI. Eligible investigators could also be in the final/no cost extension year of R01 or R01-level equivalent funding.
 - o E applicants must obtain pre-submission approval.
 - o Send your specific aims and current NIH Other Support that includes any pending support and your plan for obtaining R01 equivalent funding over the next year to Cynthia Wetzel, PhD (DHC manager) cynthia.wetzel@cchmc.org.
 - o The DHC leadership will review to determine if you are eligible to submit an application.

For Multi-PI projects the type of application 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, 2025. 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

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 applications.

Remember Established Digestive Disease Investigator MUST obtain pre-submission approval.

1. Face page
2. Project summary, relevance, division or institute, key personnel, and use of Human Embryonic Stem Cells.
3. Table of Contents
4. Detailed budget
 - Salary support is allowed for anyone working on the project other than the principal investigator. Principal Investigator salary support is not permitted.
 - Projects should utilize DHC supported Research Cores. Specific plans to use the cores on a fee-for-service basis should be included in the budget, where applicable.
 - Budget **can be** used for animal costs, laboratory reagents and supplies, or publication costs but **not** for travel or membership dues.
 - The budget should include **only** direct costs up to \$50,000.
 - Carryover is **not** allowed.
5. Budget Justification
6. NIH Biosketch **for PI and Co-Investigators (if appropriate).**
7. Other Support: **Provide other support for ONLY the principal investigator.** 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.
8. If applicable Response to Previous Review (**1 page**)
9. Body of Application- **5-page limit based on current NIH format.**
 - a) **Specific Aims (1/2 page).** Remember this is a ONE-year pilot project.
 - b) **Research Strategy (4 ½ pages).** Organize the Research Strategy into three sections - *Significance, Innovation and Approach* using the instructions 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:** Describe the scientific premise and rigor of the prior data for the proposed project as well as explain how the proposal will address an important problem or a critical barrier in the digestive disease 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 digestive disease field.

- **Approach:** Describe and provide the rationale for the overall research strategy, experimental design, and methodology used to accomplish the specific aims of the project. Provide the justification for sample sizes and the feasibility of obtaining the sample(s). Include a statistical analysis plan that addresses the study hypotheses and aims, as well as specifying the primary and secondary study outcomes. Include preliminary data as appropriate. Discuss any potential problems and solutions. In keeping with current NIH guidelines, describe plans to address weakness in the rigor of prior research that serves as support for the proposed project, methods to ensure robustness and unbiased results, validation of key biological resources and explain how relevant biological variables (i.e. sex) are factored into the research design and analysis for studies involving vertebrate animals or humans.

[See NIH for more information regarding rigor and transparency](#)

[See NIH Scientific Rigor Examples](#)

Applying for 2nd Year Funding. If applicable 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.

10. Literature cited. Provide full details of literature cited including full title and authors.
11. Human Subjects. Include Inclusion of Individuals Across the Lifespan, Inclusion of Women and Minorities, Recruitment and Retention Plan, Study Timeline, Planned Enrollment Report, Protection of Human Subjects, and Data Safety and Monitoring Plan required for a NIH application. If your application is selected for funding, you will need to submit all sections required for a NIH application.
[See PHS Human Subjects and Clinical Trials instructions for more information](#)
12. Vertebrate Animals. Include 4-point narrative required for NIH application. [See NIH instructions](#)
13. Select Agent Research. See **Section 6** of the [NIH instructions for more information](#)
14. Resource Sharing Plan. See **Section 10** of the [NIH instructions for more information](#)
15. Authentication of Key Biological and/or Chemical Resources. See **Section 12** of the [NIH instructions for more information](#)
16. Data Management and Sharing Plan. If your application is selected for funding, you will need to submit a Data Management and Sharing Plan. See [NIH Writing a Data and Management Plan for more information](#).
17. 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 research themes of the DHC](#):
 - a) Mechanisms of Liver Disease; b) Digestive Disease and Immunity c) Stem Cell and Organoid Modeling of Digestive Disease
18. Brief description of the proposed use of DHC supported Research Cores (if any). Click on links below for more information.
 - a) [Gene Analysis Core](#)
 - b) [Integrative Morphology Core](#)
 - c) [Stem Cell/Organoid and Genome Editing \(SCOG\) Core](#)
 - d) [Clinical Component- Data Management/Analysis and Biobank](#)

19. Letter of support from your Division Director stating availability of resources and time commitment.
20. Letter(s) of support from any consultants.
21. 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. Members will follow strict conflict of interest guidelines. Selection process will consist of 2 steps:

- 1) Identify approximately 6 applications based on their scores from the review panel
- 2) Brief presentation of the research plan by the top scored applicants to the DHC External Advisory Board (EAB).

The EAB will make the final selection.

The main criteria for the review of the application are:

- Scientific merit of the application.
- Type of application 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 DHC focus areas:
 - Mechanisms of Liver Disease
 - Digestive Disease and Immunity
 - Stem Cell and Organoid Modeling of Digestive Disease?

It is strongly recommended that investigators planning to submit an application have a consultation with the DHC supported Data Management and Analysis Collaborative for statistical analysis prior to submission.

Applications that are recommended for presentation to the EAB will be reviewed by the DHC supported Data Management Analysis Collaborative for statistical methods and implementation. The comments will be sent to those presenting to the EAB prior to their presentation. Applicants are encouraged to address reviewer's comments during their presentation. Approval from the Data Management Analysis Collaborative will be required before funding starts.