



The Texas Medical Center Digestive Diseases Center Pilot/Feasibility Program 2022-2023 Application Instructions

Date: July 18, 2022

To: Texas Medical Center Faculty
DDC Members

From: DDC Internal Advisory Committee:

Robert Bresalier, M.D.
Douglas Burrin, Ph.D.
Hashem B. El-Serag, M.D., M.P.H.
Sarah Blutt, Ph.D.
Margaret Conner, Ph.D.
Mary K. Estes, Ph.D.
David Y. Graham, M.D.
Hemant Roy, M.D.
Cynthia Ju, Ph.D.

Fasiha Kanwal, M.D. MSHS
Jason Mills, M.D., Ph.D.
Geoffrey Preidis, M.D.
J. Marc Rhoads, M.D.
Benjamin Shneider, M.D.
Noah Shroyer, Ph.D.
Cullen M. Taniguchi, M.D., Ph.D.
James Versalovic, M.D., Ph.D.

Subject: Instructions for Application — Funding for Pilot/Feasibility Projects

The Texas Medical Center Digestive Diseases Center (DDC) is pleased to announce the availability of funds to provide seed money for pilot/feasibility (P/F) projects in the area of GI-related research. These funds will be awarded on a competitive basis. We anticipate funding four to five projects at approximately \$35,000 to \$50,000 each (direct costs only – indirect costs waived). Project support is provided in part NIH P30DK056338.

A Notice of Intent must be submitted by 5:00 pm CST on Friday, August 26, 2022. The full application is due by 5:00 PM CST on Friday, September 30, 2022. The awards will be for 1 year, with the option of competing for a second year of support. The earliest start date for awards is January 1, 2023.

The overall theme of the DDC is “Molecular mechanisms and outcomes of injury, infection, or metabolic dysfunction of the digestive system” with digestive-disease-related subthemes centering on:

- Infection (including host-microbe interactions and microbiome)
- Injury (including tumorigenesis and stem cell response)
- Metabolism (including diseases associated with obesity and the gut-brain axis)

Proposed pilot projects should relate to this theme.

ELIGIBILITY

All faculty members from the Texas Medical Center are eligible. Faculty members at other institutions are eligible if they submit a grant that collaborates with a faculty member at the Texas Medical Center who is also a member of the Digestive Diseases Center. Trainees who are recipients of an NRSA individual award (F32) or are supported by an institutional training grant (T32) are eligible for P/F funds, if they are in their last year of training, have had at least one year of research laboratory experience, and have suitable expertise and independence to

design and carry out the planned experiments. Trainees also should have a commitment from a senior scientist to sponsor their projects and assurance of future faculty appointment from Section/Dept Head. Trainee applicants for pilot projects are not required to be United States citizens or possess a permanent resident visa. Funding preference will be given to junior faculty. The purpose of these grants is to help young investigators establish an independent research program and to encourage the involvement of established investigators not currently working in the GI area. It is highly recommended that members of the DDC Advisory Committee (listed above) be consulted during the preparation of applications.

The funds are not meant to be used for training purposes or to provide interim funding for an established program suffering a lapse in grant support. These projects may support (1) new investigators without current or past NIH research support who are seeking to obtain preliminary data to establish a research program in GI-research, (2) established, funded investigators with no previous work in digestive-disease related areas who wish to test the applicability of their expertise to a digestive disease-related problem, or (3) established investigators in digestive diseases or digestive disease-related areas who wish to test the feasibility of a new or innovative idea which constitutes a *significant departure* from their funded research and which initiates a new collaboration with another researcher in digestive diseases. Someone with current GI funding is eligible only if the project is an entirely new research direction or they are a collaborator with another GI researcher in digestive diseases. If an applicant is associated with a group led by a more senior investigator, a letter must be provided by the group leader, identifying areas of overlap and autonomy. The Review Committee should be convinced that the proposed research is an independent departure for the applicant. If the PI of the Pilot/Feasibility project has not had a previous major federally funded grant, the PI should identify a mentor. The mentor should provide a letter describing a mentoring plan, the mentor's commitment to the individual, and an evaluation of the project. **All junior faculty and trainee applicants should have 50% protected time for research if the project is funded.** Junior faculty applicants that have less than 50% protected time for research should contact Dr. Burrin before submitting the Notice of Intent.

The pilot/feasibility funds are meant to permit preliminary testing of new ideas. An application is not eligible if the proposed work has been previously supported by external, major peer-reviewed funding. If an application to external granting agencies on the same work is currently pending and is subsequently awarded, any approved and unspent DDC funds must be returned at the time the external grant is activated.

An important goal of the DDC pilot/feasibility program is to get junior investigators connected with other DDC faculty and foster increased involvement of the PI in DDC activities, such as the GI forum and other pediatric GI training events in the Texas Medical Center. We expect all PF awardees to become involved and attend these DDC and GI training activities on a regular basis.

Current DDC pilot/feasibility fund awardees will be eligible to apply for a second year of support. However, it is expected they will have significant progress to report and a strong justification for requesting additional support. **A third year of support will not be provided for any project.** An investigator may receive pilot/feasibility support for new projects only once in any five year period.

CRITERIA FOR EVALUATION OF APPLICATIONS

The criteria used in evaluating an application are the same as those generally applied in competition for funding at the national level: (1) the novelty and significance of the basic or clinical information being sought, (2) its relevance to GI-research, (3) whether the specific aims are logical and the approach valid and adequate, (4) the feasibility of the procedures outlined in the application, (5) the probability that the project will lead to a grant application for external funding, (6) the potential for clinical and basic science interactions, (7) the scientific expertise of the applicant to perform the proposed research, and (8) the use of DDC cores. For junior faculty and senior postdoctoral fellows, there must be a mentoring plan outlining your primary mentor, plans to obtain independent funding, and how you intend to become actively involved in the DDC. An individual who wishes to carry out a project for which he/she lacks technical expertise should obtain that expertise by collaborating with other scientists within the Texas Medical Center, and a letter of collaboration should be included in the

application. Applicants are encouraged to consult members of the DDC Internal Advisory Committee for advice on preparing these applications. Applicants should also seek guidance from applicable DDC Core Directors involving their projects.

NOTICE OF INTENT

All persons interested in submitting an application should initially submit a Notice of Intent with a tentative application title, the name of the PI, any co-PIs, and their affiliations via the online system. Questions can be directed to Sara Tristan at escamill@bcm.edu. The online system will be made available by August 1, 2022.

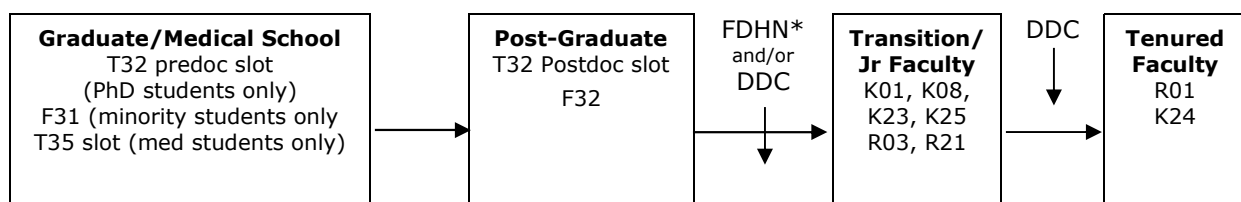
The Notice of Intent must be submitted using the online system by 5:00 pm on Friday, August 26, 2022. A notice of intent is required for any interested applicant. Notice of Intents will be reviewed for funding eligibility. Any applicant, whom does **NOT** meet the minimum qualifications to submit an application, will be contacted before September 2, 2023. All other applicants are encouraged to move forward with their full application. If you are unsure of eligibility, please contact Doug Burrin, Ph.D., at doug.burrin@usda.gov, or Sara Tristan, B.S. at escamill@bcm.edu.

FORMAT OF THE APPLICATION

The body of the grant must be no more than five (5) single-spaced pages (for **new** applicants; see items #7 and #8 below for **second year** and/or **resubmissions**) with standard type size of 11 to 12 points (no more than 15 characters per inch) and margins of 1 inch. The applications should follow the general format of NIH research project applications (RO1) and be submitted on current NIH forms. One additional summary sheet page is for the DDC only (see below). Each application must contain the following items:

1. Summary sheet (DDC form attached) (1 page). This will be given to all reviewers.
2. Table of Contents (NIH form page 3).
3. Detailed budget for the application on a NIH RO1 budget page, with justification for each major item. Pilot projects should plan on taking advantage of DDC core facilities; specific plans to use the cores and funds to pay core fee-for-service charges should be included in the budget. (Listing of cores attached). **In general, PI salary and travel should not be included and strong justification will be required for any piece of equipment** (maximum, 1 page for budget justification). *DO NOT SUBMIT A MODULAR BUDGET.* Indirect costs will not be paid.
4. NIH-5 page biosketch of the applicant with a list of recent publications and previous projects.
5. Sources and amounts of funds currently available to support research on this or related subjects by the applicant and/or by a senior investigator with whom the applicant is associated. If such funds exist, the applicant should state clearly why DDC P/F funds are needed. List any pending applications at granting agencies with potential budgetary overlap.
6. Body of application for **NEW** applications (maximum of 5 pages) on NIH continuation pages:
 - Specific aims (Approximately half-page, single-spaced).
 - List numerically and make them brief and to the point.
 - The aims should address specific hypotheses rather than just gathering data or doing a “fishing expedition”. List the hypotheses your aims address.
 - a. Significance and Innovation (1-2 pages maximum):
 - Briefly describe why this work is important and how it addresses a critical problem or scientific question in the field.
 - How does this work challenge existing paradigms with novel approaches or methods?
 - Make a synthesis from your literature review rather than just a listing of a string of facts.
 - Be concise in your review of the literature and make judicious use of subheadings/bold font. Only list the key literature has led to your hypothesis.
 - b. Preliminary Studies (No more than 1 page, single-spaced):
 - Preliminary data is not required in the grant, since this is a pilot/feasibility grant.

- If you have relevant preliminary results, these should be included and indicate whether it was done by you or someone else. If there is key preliminary data to show feasibility of your idea this should be included within this section of the application. You can put additional supporting figures/tables etc. in the Appendix, but do not put critical information in the Appendix to subvert the page limits.
- c. **Research approach** (Study design, methodology, data analysis and any problem areas anticipated) (1-3 pages, single-spaced):
- In format, this should parallel that of your Specific Aims section, e.g., if you have two specific aims, you will have two subheadings in this section where you describe the design of experiments related to each specific aim. If there are general methods that apply to all specific aims, identify them as such under a separate heading.
 - Explain your rationale for your experimental design and for choosing one particular approach over another.
 - There is no need (or space) to give minute details of common methods such as enzyme assays, RNA preparation, Northern blots, etc. Instead, state briefly the type of method that will be used and indicate what results will be expected.
 - Describe how you will analyze your results and address the potential pitfalls and potential problems you may encounter. Applicants are strongly advised to seek consultation with the DDC Study Design Core during the application-writing phase to assist with study design, power analysis and statistical analysis. Applications should also consider elements of rigor and reproducibility. Contact Fasiha Kanwal, MD, MSHS, Core Director, at kanwal@bcm.edu for more information.
7. Body of application for a **second year of funding** (maximum of 6 pages):
Applications for a second year of funding must include a brief progress report (1 page) in addition to following the instructions outlined above for new applications.
8. Body of application for **resubmitted** applications (maximum of 5 ½ pages):
Include a brief introduction (half page), which addresses previous critiques for all resubmitted applications, in addition to following the instructions outline above for new applications.
9. Literature cited:
- Give full details of all references used, including authors and titles of articles.
 - List numerically, either in order of citation in the text or alphabetically.
10. **Long term goals and mentoring plan:** Briefly describe the long-term goals of the research project that you hope to develop, if the pilot project is successful. Provide a short rationale for the proposed pilot project and planned research program, based on past experience of the applicant (maximum, 1 page). Indicate your plans for future grant submissions to the NIH or other national organizations. If you have not previously had an extramural grant, you should identify a mentor and outline a mentoring plan. The diagram below outlines a common pathway for funding for GI researchers. Also, describe how you plan to become more involved in DDC and/or BCM Pediatric GI training program activities, such as GI Forum, Pediatric GI workshop, Pediatric GI Journal Club.



*Fdns – Foundations, i.e., FDHN (The Foundation for Digestive Health and Nutrition), ALF, CCFA, CDHNF, etc.

11. **Important: Describe how this project relates to the theme of the DDC: GI infection and injury.** GI is defined as the gastrointestinal tract, liver and pancreas. *Injury* is defined as drug, genetic, ischemic, inflammatory, surgical, nutritional, or stress-induced injury to the gastrointestinal tract. *Injury* also includes gastrointestinal adaptation and stem cells.

12. **Provide a timeline of your project.** Explain how you will carry out your project over the course of funding and add any anticipated milestones that can be addressed in your annual progress report.
13. **Briefly describe the use of the DDC cores for your project.** Specifically, outline how the cores will facilitate this research. Describe how you plan to participate and become involved in the activities of the DDC, such as attending the GI Forum regularly, attending Pediatric GI Workshops and monthly Journal Clubs, and trainee lectures.
14. Appendix material (optional; maximum of 2 pages).
15. Protocols using human subjects, animals, radioisotopes or biohazardous materials must have appropriate review and approval before DDC funds can be expended. It is not necessary to obtain these approvals or a Routing Sheet before the application is reviewed. If an application is approved, all of the relevant approvals must be obtained prior to final funding.
16. For any project involving human subjects, you will be required to submit a **planned enrollment table and data sharing plan** for all nonexempt Human Subjects research. These items must be submitted before funding can be finalized.
17. **Applications require the signature of the chair of the applicant's academic unit (on the Summary Sheet).** This signature will confirm that all clinicians who are PI's will have 50% protected time to perform the research. It is not necessary to obtain institutional signatures from the Office of Research.

SUBMISSION OF APPLICATIONS

The completed application (including the Summary Sheet) should be combined into one PDF file and submitted via our online system by **5:00 p.m. CST on Friday, September 30, 2022**. You will receive a confirmation email once you have submitted your application. **If you do not receive a notification, email Sara Tristan at escamill@bcm.edu before the 5 p.m. CST deadline.**

REVIEW PROCESS

Proposals will be reviewed and rated by a Committee composed of the DDC Internal Advisory Committee (see above) plus ad hoc members selected from senior faculty at the Texas Medical Center or elsewhere. This committee is chaired by Douglas Burrin, Ph.D. He can be reached at 713-798-7049, Doug.burrin@usda.gov). Final approval for funding will be made by the DDC Internal Advisory Committee plus ad hoc members.

As the review panel will be composed of members who may not be familiar with the topic of an application, applicants are advised to avoid specialized jargon, to provide definitions and brief descriptions of sophisticated procedures, and to state clearly the hypothesis to be tested and the significance of the research.

The 2022 / 2023 Pilot / Feasibility Awardees will be announced in November 2022 by email, during our weekly seminar, and on the DDC website.

AWARD CONDITIONS

All funded PF applications should have a start date no earlier than January 1, 2023. Award letters will be sent out in November 2022. All applicable materials, protocols, enrollment tables, data sharing plans will be required before funding is completed. Any delays in funding do not constitute a no cost extension.

Funded pilot feasibility awardees are required to attend the weekly GI Research Forum. Awardees will also be required to present updates on their pilot projects after the first year of funding. In addition, awardees are required to provide an annual progress report for the following five years of their award.

Post award management questions can be directed to DDC Administrator, Sara Tristan, B.S. at escamill@bcm.edu

APPLICANT CHECKLIST

- _____ 1. Notice of Intent submitted to online system by **August 26, 2022**
- _____ 2. Applicant has consulted a DDC IAC member and Core Director about the proposed studies.
- _____ 3. Application
 - _____ a. FACE PAGE: The DDC Summary sheet with signature of your Department chair.
 - _____ b. NIH table of contents page (NIH form).
 - _____ c. NIH detailed budget page and budget justification. No indirect costs (IDC).
 - _____ d. NIH Biosketch.
 - _____ e. Current other support.
 - _____ f. Body of application (maximum 5 pages if new; 5 ½ pages if a resubmission; 6 pages if for a second year of funding).
 - _____ g. Literature cited.
 - _____ h. Long-term goals, including plans for future grant applications. Outline a mentoring plan if applicant has not had previous extramural federal funding (include letter from mentor)
 - _____ i. Letter from mentor assuring their commitment to you and an evaluation of your project plan, if applicable.
 - _____ j. Mentor's NIH Biosketch
 - _____ k. If the PI has recently been part of a group led by a more advanced investigator, a letter explaining how this project will lead to independence.
 - _____ l. Letter(s) of collaboration, if applicable
 - _____ m. Describe how project relates to the theme of the DDC.
 - _____ n. Describe use of DDC cores.
 - _____ o. Appendix.

Online Application to be submitted by 5 p.m. CST on September 30, 2022.



Texas Medical Center Digestive Diseases Center PILOT/FEASIBILITY AWARDS APPLICATION SUMMARY SHEET

Name of PI: _____ Degree: _____ Academic Title: _____

Department: _____ Institution: _____

Mail Station: _____ Phone No.: _____ Fax No.: _____ E-mail: _____

Short Title of Project (do not exceed 56 characters and spaces): _____

Type of Application: _____ Pilot project _____ Collaborative project _____

BUDGET: Supplies: \$ _____ Small Equip.: \$ _____ Personnel: \$ _____ Other: \$ _____

Total: \$ _____ (No indirect costs on these pilot awards)

Has the PI of a pilot project application recently been part of a group led by a more advanced investigator?
 Yes No (If yes, a letter citing independence of the PI for this project must be included.)

If the PI of the pilot project has **not** had a previous grant, does the PI have a mentor? Yes No
 (A letter describing the commitment of the mentor and a mentoring plan must be included.)

DDC Cores to be utilized:

- Tissue Analysis & Molecular Imaging (TAMI) Functional Genomics and Microbiome (FGM)
 Gastrointestinal Experimental Model Systems (GEMS) Study Design & Clinical Research (Clinical)

CHECK APPLICABLE BOXES:

	Yes	No		Yes	No
Human Subjects:	<input type="checkbox"/>	<input type="checkbox"/>	Biohazards:	<input type="checkbox"/>	<input type="checkbox"/>
Radioisotopes:	<input type="checkbox"/>	<input type="checkbox"/>	Animals:	<input type="checkbox"/>	<input type="checkbox"/>

SUMMARY: Write a short paragraph, **not to exceed the space below**, describing major aims of the project and the approach to be used.

APPLICANT'S SIGNATURE: _____ DATE: _____

ACADEMIC UNIT CHAIR'S SIGNATURE: _____ DATE: _____