

The Texas Medical Center Digestive Diseases Center

Date: August 31, 2009

To: Texas Medical Center Faculty
DDC Members

From: DDC Internal Advisory Committee:
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Subject: Request for Applications —
Funding for Pilot/Feasibility Projects

We are pleased to announce the availability of funds to provide seed money for pilot/feasibility (P/F) projects in the area of GI-related research, beginning in March, 2010. These funds will be awarded on a competitive basis. We anticipate funding four to five projects at approximately \$10,000–\$35,000 each (direct costs only – indirect costs waived). In the last funding cycle, six projects were funded. Project support will come from the NIH-funded Digestive Diseases Center. The awards will be for 1 year, with the option of competing for a second year of support. The theme for the DDC is **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. 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 should have a commitment from a senior scientist to sponsor their projects. Trainee applicants for pilot projects must 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 must have 75% protected time for research if the project is funded.***

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.

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. 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.

NOTICE OF INTENT

All persons interested in submitting an application should initially submit a Notice of Intent with a tentative application title, and the name of the PI, any co-PIs, and their affiliations to dfox@bcm.tmc.edu by [September 11, 2009](#).

FORMAT OF THE APPLICATION

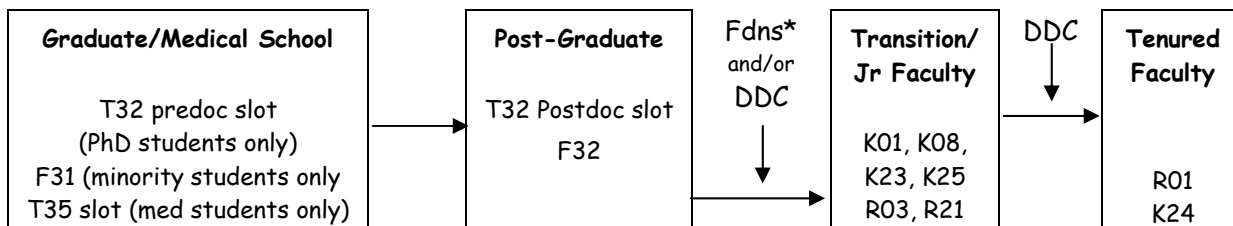
The body of the grant must be no more than five (5) single-spaced pages (for **new** applicants; see items #7 and #8 below for **second year** and/or **resubmissions**) with standard type size of 11 to 12 points (no more than 15 characters per inch) and margins of 1 inch. The applications should follow

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-3 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:
 - a. Specific aims (Approximately half-page, single-spaced. **Remember that this is for a 1-year project**):
 - 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.
 - b. Background and significance of research (2 pages maximum):
 - Briefly describe prior work that has led up to the current hypotheses.
 - Be thorough but concise in your review of the literature.
 - Make judicious use of subheadings.
 - Be sure to make a synthesis from your literature review rather than just a listing of a string of facts.
 - c. Preliminary Studies (No more than 1 page, single-spaced):
 - You may not have any preliminary data since this is a pilot/feasibility grant.
 - Briefly describe any relevant preliminary work and indicate whether it was done by you or someone else. There must be some preliminary data to show feasibility of your *idea*.
 - Summarize as necessary. You can put 1-2 figures/tables etc. in the Appendix.
 - d. Research design and methods (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. The DDC Study Design Core is available to help investigators during the application-writing phase and to assist with study

design and applications. Contact Claudia Kozinetz at 832-824-3730 or email kozinetz@bcm.tmc.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, whichever you prefer.
10. 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 following is a common pathway for funding for GI researchers:



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

11. 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. Briefly describe the use of the DDC cores for your project. Specifically, outline how the cores will facilitate this research.
13. Appendix material (optional; maximum of 2 pages).
14. 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 and submitted to the DDC prior to final funding.
15. Applications require the signature of the chair of the applicant's academic unit (on the Summary Sheet and on the Face page). This signature will confirm that all clinicians who are PI's will have 75% 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 submitted as a PDF file to Dede Fox, DDC Administrative Secretary via email, dfox@bcm.tmc.edu , by **October 12, 2009**.

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. The chair and co-chairs of this committee: Lenard Lichtenberger, Ph.D. (UTHSC, 713-500-6320 phone, Lenard.M.Lichtenberger@uth.tmc.edu), Gretchen Darlington, Ph.D. (Baylor College of Medicine, 713-798-1565, gretchen@bcm.tmc.edu), and Robert Bresalier, M.D. (MD Anderson, 713-745-4340, rbresali@mdanderson.org). 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.

CHECKLIST

- _____ 1. Intent to Apply notice submitted to Dede Fox at the DDC by **September 11, 2009**.
- _____ 2. Applicant has consulted a DDC IAC member and Core Director about the proposed studies.
- _____ 3. Application
 - _____ a. FACE PAGE Summary sheet with signature of Department chair.
 - _____ b. NIH table of contents page (NIH form).
 - _____ c. NIH detailed budget page and budget justification. No indirect costs (IDC) will be paid.
 - _____ 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 (modular, up to 4 pages).
 - _____ 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 (Infection & Injury).
 - _____ n. Describe use of DDC cores.
 - _____ o. Appendix.

*All elements above to be scanned as one PDF file, and emailed to Dede Fox at dfox@bcm.tmc.edu by **October 12, 2009**.*



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

Name of PI: _____ Degree: _____ Academic Rank: _____
 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: Cellular & Molecular Morphology Functional Genomics & Proteomics
 Integrative Biology Study Design & Clinical Research

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: _____