The Harvard Digestive Diseases Center (HDDC) will be accepting applications for new and continuing pilot and feasibility projects for the upcoming funding period (7/1/18 - 6/30/19).

**PLEASE NOTE:** A Letter of Intent is required. This allows the HDDC to verify eligibility of the applicant for this program and the relevance of the project to the mission of the HDDC. Please use the LOI form and submit, along with your updated NIH biosketch, to Amanda Reilly at: amanda.reilly@childrens.harvard.edu. LOIs will be reviewed and applicants whose projects are considered eligible will be invited to submit a full application, as described below.

**SCIENTIFIC SCOPE of the Pilot and Feasibility (P/F) Awards Program**

The Harvard Digestive Disease Center is focused on the study of epithelial cell function and mucosal biology including inflammation and host defense of the gastrointestinal tract.

We have major emphasis on the inflammatory bowel diseases, gut microbiology, and stem cell and developmental biology of the intestine, liver and pancreas in organ physiology and regenerative medicine.

Pilot & Feasibility projects will be considered for support if they relate directly or indirectly to this mission. Clinical and translational research proposals are encouraged.

Eligible projects may be in areas such as:

- cell and molecular biology that relate to epithelial structure and function in the alimentary tract, liver, and pancreas;
- epithelial-microbe interactions and pathogenesis of enteric infectious diseases;
- host defense in the GI tract, mucosal immunity and vaccine development;
- epithelial cell growth and differentiation, and stem cell biology;
- carcinogenesis in the GI tract;
- smooth muscle motility and biology of the enteric nervous system.

**UTILIZATION of the HDDC CORE FACILITIES is strongly encouraged.** These cores include:

- Core B: Microscopy and Histopathology
- Core C: Epithelial Cell Biology and Mucosal Tissue Assessment
- Core D: Gnotobiotic, Microbiology, and Metagenomics

*Visit the HDDC Website for further details, LOI form and grant application materials*

http://hddc.hms.harvard.edu/
PURPOSE of P/F PROGRAM

- Support young investigators who have not previously held independent awards (such as an RO1 and/or PO1) in carrying out independent and promising research that tests a novel research direction or hypothesis. (Type 1 awards)
- Enable young, developing scientists and/or clinicians to pursue innovative and promising pilot projects which might otherwise not have support, and which ultimately might lead to independent support.
- Enable established investigators already working in digestive disease-related research to make a substantial change in the direction of their research. (Type 2 awards)
- Entice investigators who have left the field of digestive diseases, or who have never worked in the field, to become involved in research related to digestive diseases. (Type 3 awards)
- Note: Awards for the PF program by NIH guidelines is biased to young investigators emerging into independence (Type 1 awards).

ELIGIBILITY

- New/Young Investigators are particularly encouraged to apply and to use P/F funding to gather the data needed for subsequent NIH applications.
- Although P/F projects may be related to ongoing or previous work, they cannot overlap any funded project. Ongoing work refers to established projects already funded by NIH or other mechanisms.
- Qualified candidates for Type 1 awards must show evidence for emerging independence, usually at a stage just before application to NIH for K-series Career development awards, or during the funding period of the K-award. Successful applicants will have identified Mentors in place, a Scholarship Oversight Committee in place, and career development plans leading to NIH funding by RO1 or K-award mechanisms.
- Funded Investigators already in GI related research fields (Type 2 award) must show how this project is a clear and significant departure from ongoing work. Proposals that are logical extensions of ongoing projects are not eligible.
- P/F grants are not intended to be used as bridging support.
- An investigator can be funded only once in every five-year cycle. A funded P/F project may be renewed for a second year, but competitive re-application is required.

EXPENSES FOR WHICH FUNDS MAY BE USED

Funds may be used for the following:
Technical support.
- Research supplies.
- Equipment is funded only in very rare instances where it is vital to the particular project, unique and not available in any of the HDDC core facilities. Equipment requests require a budget justification and approval by the Executive Committee.

Non-allowable expenses:
- Salaries (Investigator, Post-Doctoral)
MAXIMUM AWARD
The amount of awards varies with the availability of funds and quality of applications received. In recent years, project budgets have averaged about $25,000, direct costs. Facilities and Administrative (F&A) costs will be awarded at the rate of 25%.

APPLICATION PROCEDURE
The deadline for receipt of the Letter of Intent and NIH biosketch is November 20, 2017. Applicants will be informed of their eligibility to apply by December 14, 2017. The application deadline is January 30, 2018. All applications must be compiled and submitted as a single PDF to amanda.reilly@childrens.harvard.edu. Signed originals of the face page, budget page, IACUC and/or IRB approvals will be requested if the project is approved.

Use the NIH format. The documents to be submitted should be assembled in the order listed below. The link to the NIH forms is http://grants.nih.gov/grants/funding/phs398/phs398.html

FORMAT OF APPLICATION
- Form Page 1 (Face Page)
- Form Page 2 (Description, Performance Sites, Key Personnel)
- Form Page 4 (Detailed Budget for Initial Budget Period)
- Budget Justification (Please use Continuation Format Page)
- Biographical Sketch
- Other Support – Please include a paragraph explaining how this research proposal is a departure from your ongoing work, and from the work of your previous or current mentors or collaborators.
- Resources: please also list here the HDDC Core Facilities that you plan to use.
- The “Research Plan” section of the grant should be limited to 3 pages single-spaced. [references are not included in the 3 page limit but should be limited to essential citations]. In the Research Plan, indicate how the project will use HDDC Core facilities.
- Applicants must address aspects of Rigor and Transparency in their application, as mandated by the NIH, please see (http://grants.nih.gov/reproducibility/index.htm) for additional information. Rigor and Transparency will be a distinct criterion for review.

ADDITIONALLY
On a continuation format page, list four names that you consider appropriate to review your application. These names can be, but are not limited to, members of the HDDC and the Harvard Medical area. Please include their full name, address, email, and telephone number.
For applications for continuation of current 1-year awards
Include in the Research Plan a description of the progress you have made in the first year, as well as your plans for the proposed second year. Also include a paragraph summarizing your past and planned use of HDDC cores and describe any collaboration with Center investigators.

EVALUATION OF APPLICATIONS
Each P/F application is reviewed by selected members of the HDDC Executive Committee and the HDDC External Advisory Board, and other expert reviewers as appropriate. The entire Executive Committee considers these reviews, assigns priority scores and ultimately decides upon the awarding of the grants. Funding decisions are based upon scientific merit and the appropriateness of the project to the goals of the P/F program.

Harvard Digestive Diseases Center

RESPONSIBILITIES OF AWARDEES

- Awardees will be required to submit a written progress report in March 2019 for our annual External Advisory Board meeting. You will be asked to submit an updated version of this progress report by August 14, 2019 for inclusion in the HDDC non-competing renewal application to the NIH.
- Awardees are encouraged to use HDDC Core services.
- Awardees are expected to participate in HDDC activities by attending research conferences and generally becoming involved in scientific exchange within the program.
- You will be required to present your work at our annual fall scientific retreat featuring all PF grant recipients. This occurs in November / December of the year following termination of the PF award (November 2018 for awards made July 2017)
- Selected PF recipients will be invited to present at our Annual External Advisory Board meeting in of April of the current Award.
- Harvard Digestive Diseases Center support must be acknowledged on all publications resulting from the research. This may take the form of "Supported in part by the Harvard Digestive Disease Center, NIH Grant P30 DK34845."

CONTACTS
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