



## 2019-2020 MID-ATLANTIC NORC PILOT & FEASIBILITY (P/F) PROGRAM

### Eligibility Criteria & Guidelines for Submission

***Please review ALL criteria and guidelines below prior to and during the preparation of both the Letter of Intent and the Full Project Proposal. Thank you!***

#### Eligibility for new applicants:

Applicants for these awards must be faculty at an academic institution affiliated with the Mid-Atlantic NORC and must fulfill one of the following eligibility criteria:

- 1) [New investigators](#) without current independent research funding;
- 2) Established investigators in the field of nutrition/obesity who are proposing a project that represents a significant departure from their previous/current work;
- 3) Established investigators in other fields who wish to apply their expertise to nutrition and obesity research.

New investigator applicants must have a doctoral degree and at least two and preferably three or more years of post-doctoral experience, and a faculty appointment by 9/1/19. New investigators should be embarking on an independent research career. Post-doctoral fellows are not eligible, unless they are transitioning to faculty by 9/1/19. For those in this situation, written documentation of the faculty appointment (including effective date) must be submitted with the full application.

#### Aim of the P/F Project:

The aim of a P/F project is to provide convincing data for future proposals to the NIH or other national agencies. Investigators are encouraged to undertake high risk/high gain projects that have the potential to develop but for which no preliminary data of feasibility are currently available. Nevertheless, the capability of the PI (and his/her collaborators) to undertake such a project should be clearly outlined.

P/F projects are strongly encouraged to take advantage of our Core laboratories. These are: 1) Administrative Core, including Biostatistics and Medical Informatics (BMI) Subcore; 2) Clinical and Translational Research (CTR) Core; 3) Molecular Genetics and Functional Genomics (MFG) Core. 4) Community Pediatric Nutrition Obesity Research Core. Information on these cores can be found at our web site:

<http://www.medschool.umaryland.edu/norc/Cores/>

All applicants must be willing to actively participate in Mid-Atlantic NORC Center activities, including seminars, workshops, and symposia, and to present NORC seminars describing their work. Each P/F awardee will be assigned a committee and must be willing to meet regularly with the committee members (up to 3 times per year, depending on progress).

#### Projects Submitted Elsewhere:

It is acceptable to submit a project that is currently under review elsewhere; however, receipt of funding by another agency for the same project will preclude Mid-Atlantic NORC funding.

## **Application Process and Deadlines:**

Review of the application will take place in two stages:

- 1) Letter of Intent, and
- 2) Proposal.

### **Stage 1) Letter of Intent - DUE BY NOON ON MONDAY, MARCH 4, 2019**

Letters of Intent should be no longer than 2 pages and should:

- 1) address the eligibility of the investigator for the award according to the above stated criteria,
- 2) provide a brief description of the project; specific aims; and explain briefly what you will do with the pilot data and where this research will lead (investigator's plans for submission to NIH or other federal funding)
- 3) have a complete academic CV attached. An NIH-style biosketch, indicating current and pending grant awards, is optional at the Letter of Intent stage, but is required should the candidate be invited to submit a full application. The CV and NIH Biosketch (if submitted with the LOI) do not count as part of the 2-page limit for the Letter of Intent.
- 4) Each applicant submitting a Letter of Intent must also provide the names, academic institutions and contact information (email and phone) for 2 - 3 researchers in their field of study, who would be well equipped to fairly judge the scientific merit of the application. These individuals should be from outside of the applicant's academic institution and outside of the Mid-Atlantic NORC, if at all possible. Reviewer suggestions will be taken into account when reviewer selections are made; however, suggesting a reviewer will not guarantee that the reviewer will be invited to review the applicant's proposal. The names and contact information of potential reviewers is requested **WITH THE LETTER OF INTENT (due by NOON on MONDAY, MARCH 4, 2019)** so that potential reviewers can be contacted early and lined up to review applications in advance. This way, the review process can begin as soon as the full proposals are received.
- 5) If the project has been previously submitted to the Mid-Atlantic NORC, any issues raised in prior critiques of the project should be addressed in the Letter of Intent.

### **Stage 2) Proposal – DUE BY NOON ON MONDAY, MAY 13, 2019:**

After review by the Mid-Atlantic NORC Executive Committee to determine eligibility, scientific potential and relevance of our center's mission, a 5-page proposal will be requested of those invited to apply. Notification regarding each candidate's eligibility to submit a proposal should go out on or around the week of March 18, 2019 and **5-page proposals will be due no later than noon on Monday, May 13, 2019.**

### **Guidelines for Initial (Year 1) Submission of Mid-Atlantic NORC P/F Proposals**

*(Note: these grants are renewable for a 2nd year of work upon submission of a progress report. You may plan 2 years of work, although an award for the first year does not guarantee that you will receive funding for the second year, so plan your research accordingly such that the relevance of the first year of work is not contingent on having a second year of funding. Guidelines for requesting 2nd year of P/F funding appear in the following section.)*

- 1) **Organization of Proposal/Page Limits:** Organize the proposal as a 'mini' NIH grant. LIMIT 5 pages maximum for the body of the proposal; additional pages, such as Title Page/Table of Contents, References, Budget & Budget Justification, Project Timeline, and any necessary letters of collaboration/support may be in addition to the 5 pages.
- 2) **Budget/Budget Justification:** Please see the funding guidelines below.

- Patient-based clinical projects (i.e., projects involving the recruitment of human research subjects who will receive interventions and/or donate research specimens). Such projects may request funding at the maximum level of \$50,000 per year.
- Laboratory-based research projects (e.g., animal physiology/pharmacology and/or molecular cell biology projects). Such projects may request funding at the level of \$35,000 per year.
- Analysis of existing databases. Such projects may request funding at the level of \$25,000 per year.

Include a detailed budget based in the aforementioned guidelines (with budget justification) for the 1st year of work only (with no more than \$5,000 going towards salary support for the PI and/or Co-I). **Please note that P/F grants do not pay indirect costs within UMB or outside.**

**3) Specific Aims (maximum ½ page):**

- What is your broad, long-term objective?
- What is the hypothesis being tested/novel method being developed, and why is it important to progress in the field?
- What are your specific objectives for this project?

**4) Background and Significance (~1.5 pages):**

- Briefly, critically evaluate the literature stating what is known and what gap in knowledge are you addressing.
- Relate the specific aims of your project to your broader objectives, explaining their importance to the scientific field/clinical relevance.

**5) Preliminary Results (½ - 1 page):** Provide preliminary data relevant to:

- The rationale for your project (if available).
- Your ability to conduct the proposed work.

**6) Experimental Design and Methods (2-2.5 pages):**

- What are you planning to do and how? (*Note: detailed methods are not needed unless new and/or critical to the research plan.*)
- How will the data be statistically evaluated?
- What are the expected results, potential pitfalls and future directions?
- How will you prioritize experiments?

**7) Project Time Line:** The approximate projected start date of this cycle of awards is September 2, 2019.

(See [instructions for PHS 398](#) for a more detailed description of how to write the proposal.)

**Guidelines for Submission of Mid-Atlantic NORC P/F Year 1 Progress Report and Proposal for Year 2 Funding**

**1) Restate your aims:**

- What is your broad, long-term objective?
- What is the hypothesis being tested/novel method being developed, and why is it important to progress in the field?
- What are your specific objectives for this project?

**2) Provide a detailed year 1 progress report (up to 5 pages, as needed):** (*Total length may exceed 5 pages if 5 full pages are needed to describe progress.*)

**3) Define goals for the 2nd year:**

- What are you planning to do in year 2 and how? (*Note: detailed methods are not needed unless new and/or critical to the research plan.*)

- How will the data be statistically evaluated?
- What are the expected results, potential pitfalls and future directions?
- How will you prioritize experiments?

**4) Justify any changes in aims from those in the year 1 proposal**

**5) Provide a full Budget with Budget Justification for the 2nd year** *(with no more than \$5,000 going towards salary support for the PI and/or Co-I)*

**6) Report on expenditures from the 1st year:** Be sure to account for any carryover from year 1.

**PLEASE NOTE** that any P&F project that propose a clinical trial of more than minimal risk requires prior approval from NIDDK. If your PF project is considered to be a [clinical trial](#) and your project is awarded, you will be asked to provide the following additional information prior to the project start date, September 2, 2019.

- IRB approval letter
- Copy of the IRB
- Clinicaltrials.gov registration number
- Eligible population with sample size and power calculation
- [Data and Safety Monitoring Plan \(DSMP\)](#)
- Project Enrollment Tables
- Project milestones
- Clinicaltrials.gov registration number (for clinical trials only)

**Submitting Letters of Intent and Proposals**

Letters of Intent (LOI) should be submitted **via online** portal:

<https://umbforms.wufoo.com/forms/norc-pilot-feasibility/>

**(Note: FULL Proposals will be submitted via online application ONLY – details of online application process will be sent to all eligible candidates submitting a LOI)**

**DEADLINES: LETTERS OF INTENT: NOON MONDAY, MARCH 4, 2019;  
PROPOSALS: NOON ON MONDAY, MAY 13, 2019**