

MEMORANDUM

TO: UAB FACULTY

FROM: Stephen Barnes, PhD, Director- UAB NORC Pilot & Feasibility Program
Martin Young, DPhil, Associate Director – UAB NORC Pilot & Feasibility Program
Tim Nagy, PhD, Program Director- UAB NORC

DATE: March 6, 2018

SUBJECT: RFA - Nutrition or Obesity-Related Pilot Feasibility (P/F) Studies

UAB's Nutrition Obesity Research Center (NORC) will fund at least **4 nutrition-related P/F studies at up to \$35,000/year**. A second year of funding is possible through a competitive renewal process. (Renewal applications will be considered from investigators currently funded by the NORC P/F program. These applications should show substantial progress in the aims of the original application and propose important new aims that further enhance the prospect of extramural funding. Those seeking a second year of funding should apply with the regular P&F procedure.)

Research Focus: The P/F studies may focus on **any area of research related to nutrition or obesity** and are designed to provide initial project support for new investigators; allow exploration of possible innovative new directions for established investigators in nutrition sciences or obesity research that represent a *significant departure* from ongoing funded research; and stimulate investigators from other areas of endeavor to use their expertise for nutrition/obesity research.

Eligibility: P/F funding is intended to support full-time UAB faculty members who are new investigators without current or past NIH research project support (those below the rank of Associate Professor); established investigators with no previous work in nutrition or obesity research; or established investigators in nutrition/obesity with a proposal to test an innovative idea representing a significant departure from ongoing research interests. P/F awards may be made to post-doctoral fellows. However, generally, post-doctoral fellows will only be competitive when such individuals are preparing to transition to a faculty slot at UAB. Post-doctoral fellows wishing to apply are strongly encouraged to meet simultaneously with their UAB faculty mentor and the P/F and/or NORC director prior to submitting a proposal. PI's (Postdocs, Instructors and Asst. Profs.) must identify a senior faculty mentor, from the NORC members, who has a strong record of NIH funding as a PI in an area related to the proposed research and who will agree to provide guidance throughout the conduct of the proposed study. Priority will be given to applications that demonstrate close relevance to the NORC mission (www.norc.uab.edu), NORC core facility usage (required), and likelihood of future R01 funding.

Procedure: Please provide a title, PI and an abstract (<500 words) of intent that highlight the background and significance, hypothesis, specific aims, experimental design and procedures of the project including relevant statistical analyses. Please submit the P&F Application Form and a copy of the PI's NIH Biographical Sketch to <http://www.norc.uab.edu/pandf/letterofintent>, by **April 6, 2018**. (The "application" form is located on this [webpage](#). Please convert to PDF and use the "upload" function at the "Letter of Intent" page for submission). Our committee will review all abstracts and select the most

competitive for development of a five-page application plus supporting materials for a final round of selection. The full application will be due **May 4, 2018**. Specific instructions will be provided to those whose abstracts are selected.

Investigators are encouraged to contact Dr. Stephen Barnes (sbarnes@uab.edu; 4-7117), Dr. Martin Young (martinyoung@uabmc.edu; 4-2328) or Dr. Tim Nagy (tnagy@uab.edu; 4-4088) to determine their eligibility and the appropriateness of their project.

Acceptance of funding will indicate agreement to submit a grant application for extramural funding to continue the project, and to provide written progress reports at 6-month intervals.

UAB NORC Cores

The Nutrition Obesity Research Center (NORC) is supported by four shared core resources. The cores represent distinct units with complementary physical and personnel resources that operate in an interactive pattern. The cores are:

- A. **Metabolism Core** (link) The Metabolism Core was designed to provide state-of-the-art assessments of human energy expenditure, substrate metabolism, body composition, body fat distribution, and bone quality; to provide cost-effective, centralized analytical services to ongoing funded and pilot research projects; to promote multi-disciplinary research and training in clinical nutrition and obesity across the UAB campus; and to offer training, advice, and instruction to students, fellows, and investigators.
- B. **Animal Models Core** (link) The Animal Models Core (AMC) provides specialized expertise in the use of animal models and state-of-the-art instrumentation to facilitate animal research related to nutrition and obesity. The AMC is a unique resource for investigators with services and resources offered not available elsewhere on campus. The Specific Aims of the Core are:
- To provide expertise in the use of animal models for nutrition/obesity research;
 - To provide state-of-the-art instrumentation and methodology for the determination of energy balance (food intake, energy expenditure, activity, and core body temperature);
 - To provide state-of-the-art instrumentation and methodology for the determination of body composition (dual energy X-ray absorptiometry, quantitative magnetic resonance, and micro-computed tomography);
 - To provide cost-efficient services to Core users; and
 - To promote interactions among investigators and to provide training in animal models and phenotyping methods. Subcores supported by the Animal Models Core (links):
- UAB NORC Small Animal Phenotyping
 - UAB Transgenic Mouse Facility
 - UAB NORC Aquatic Animal Research Core
- C. **Biostatistics Core** (link) The Biostatistics Core provides statistical consultation on study design, research proposal development and manuscript submission; provides statistical analyses for NORC projects including statistical genetics, and interfaces with other research cores on the UAB campus; participates in teaching and training activities of the NORC; and develops methodologies for novel experimental designs for members in the field and statistical analyses as needed.
- D. **Physical Activity Core** (link)

- Specific Aim 1: Provide UAB investigators guidance concerning exercise testing and training and with research-ready resistance and aerobic exercise equipment to allow for the conduct of exercise studies among children, adults, obese persons, and other populations.
- Specific Aim 2: Provide UAB investigators with guidance concerning ways to measure free-living PA, as well as provide an array of resources and trained personnel to allow them to accurately measure free-living PA among children, adults, obese persons, and other special needs populations.

The NORC cores are designed to support the following groups:

NORC Pilot/Feasibility Study recipients; NORC Named New Investigator; and Established investigators whose area of research interest is in concert with that of the NORC and who are seeking the services of experts and/or access to services which are not available within their academic units or which can be provided in a higher quality and more cost-efficient manner.

The cores benefit NORC investigator's research efforts by enhancing:

- Quality through access to state-of the art research facilities and specialized expertise, with quality control of study procedures;
- Capability with significantly greater scientific gain through the integrated approach, fostering collaborative efforts among multiple disciplines;
- Efficiency with substantially reduced cost and investigator's time commitment by accessing centralized resources compared to operating independent laboratories and hiring separate faculty/staff; and
- Enrichment by providing investigators and their technical personnel opportunities to learn and to further develop new research methodologies

Prior Approval Guidance for NIDDK UAB NORC Pilot and Feasibility (P&F) Projects Proposing Clinical Trials of More Than Minimal Risk

The following guidance should be followed for requesting prior approval of UAB NORCP&F projects that propose clinical trials with more than minimal risk. Note: These projects MUST receive written prior approval from NIH prior to award.

A clinical trial (CT) is minimal risk IF verified by the institution's IRB. Note, "minimal risk" is often defined as:

"A trial where the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

Prior Approval Submission:

For a Clinical Trial that is more than minimal risk, the P30's institutional business official must provide the following materials to the NIH Program Official and Grants Management Specialist prior to award of the P&F project:

- PI Name and Position/Title
- Project Title
- Brief description of the project purpose/aims, intervention(s), outcomes/endpoints, and eligible population with sample size and power calculation (1-2 pages)
- Data and Safety Monitoring Plan (DSMP) (refer to [DSMP Guidance](#), and see sample DSMP attached)
- Project Enrollment Tables
- Clinicaltrials.gov registration number

Timeframe for Submission:

Prior-approval requests may be submitted at any time on a rolling basis during the budget period. To allow time for the NIDDK review, requests should be submitted by the institutional business/signing official 4-6 weeks in advance of anticipated award.

Relevant IRB approval documentation must be submitted to NIH prior to initiation of recruitment.