**“Nutrition, Obesity and Metabolic Health Throughout the Lifespan”**

**2025 NORC PILOT AND FEASIBILITY GRANT APPLICATION INSTRUCTIONS**

# Overview:

The objective of this Pilot and Feasibility (P&F) grant RFA is to support research in two different funding opportunities for ***early-stage scientists*** and ***multidisciplinary teams***:

**1)** Conducting research projects to develop preliminary data and/or novel methods involving **nutrition and/or obesity-related research**.

**2)** Exploratory research relevant to obesity and/or nutrition using the existing data and biospecimens that are stored in the **Pennington/Louisiana** [**NORC Biorepository**](https://my.pbrc.edu/NORC/NORCRepository/Landing).

A maximum of 2 grants will be funded within each of these categories (development of preliminary data/novel methods, and use of the Biorepository) for 1 year. Budgets for developmental grants or novel methods are expected to be $40-50K with biorepository grants in the $10-20K range.

1. **Research Projects**

The highest priority will be given to translational research projects related to nutrition and/or obesity. The P&F awards are intended to generate preliminary data for the investigator to obtain extramural research funding from the NIH (e.g., K01, R01). We **encourage investigators** to approach problems relevant to our understanding of metabolism and function while increasing our understanding of the basic and clinical aspects of nutrition in the etiology, pathophysiology, therapy, and prevention of diseases.

# 2.  NORC Biorepository

# Background:

The Pennington/Louisiana [NORC Biorepository](https://my.pbrc.edu/NORC/NORCRepository/Landing) is a rich scientific resource with archives of unique, de-identified clinical data and quality biospecimens acquired from human subjects’ research studies conducted at Pennington Biomedical Research Center over the last 4 decades. Pennington Biomedical studies are well-known for their state-of-the-art measures including body composition assessments with dual energy x-ray absorptiometry, abdominal fat distribution and ectopic fat deposition using magnetic resonance, energy expenditure with indirect calorimetry and stable isotopes and evaluation of glucose homeostasis with euglycemic, hyperinsulinemic clamps. Our Center is also renowned for its conduct of rigorous randomized controlled trials such as over- and under-feeding, aerobic and resistance exercise, altered diet composition and bariatric surgery, and studies in specialized populations such as children, adolescents, nonagenarians, diverse groups, and pregnant women.

The Biorepository includes data and biospecimens from trials centered around obesity and nutrition and those funded by the National Institutes of Health, Department of Defense, United States Department of Agriculture, American Heart Association, American Diabetes Association and other government and non-profit organizations.

As of October 2024, data from >13,500 unique subjects and >105,000 richly-phenotyped biospecimens from 196 clinical studies are stored in the Pennington/Louisiana NORC Biorepository and are available to the scientific community. The descriptions and access to the available datasets and biospecimens within the Pennington/Louisiana NORC Biorepository can be found [here](https://my.pbrc.edu/NORC/NORCRepository/Landing). This funding opportunity will allow investigators to generate preliminary data for subsequent grant proposals and publications, thereby maximizing the scientific value of the biorepository.

**Who is Eligible?**

Full-time Associate or Assistant Professors, and senior post-doctoral fellows who meet the following criteria:

• Early-stage investigators who do not have current or previous NIH (or equivalent) independent research support (excluding fellowship or career development awards).

* Senior postdoctoral fellows who: a) will be part of the institution for at least 1.5 years at the time of award, b) have plans for extramural funding, and c) have plans for a career in an academic research setting.
* Teams of junior (faculty or senior postdoc) and senior faculty (senior as mentor only) working together to tackle a question of high priority to the NORC.
* Collaborative teams between basic, clinical, and population researchers working together to develop translational studies that pursue questions of high priority to the NORC. Collaborative projects with multiple areas of expertise are strongly encouraged.
* If you have previously been awarded a NORC P&F grant, scrutiny will be given to the novelty of the proposed study and overall progress towards independent funding.

*The P&F program values principles of equity, diversity and inclusion and all interested investigators, including those from underrepresented groups, are encouraged to apply. There is no citizenship requirement for P&F recipients but visiting scientists with whom the center or other Louisiana Institutions will not have a long-term collaborative relationship will not be considered for support. Applicants must hold a Ph.D., M.D., or equivalent degree, and have completed at least 1.5 years of postgraduate work relevant to the desired research experience.*

**Key Dates**

**Initial Email Announcement: December 16, 2024**

**Letter of Intent Due: Extended to February 14, 2025** <http://norcfunding.pbrc.edu>

**Invitation to present on: March 24, 2025**

Select LOIs will present (see instructions below)

**Full Application Due: April 7, 2025** <http://norcfunding.pbrc.edu>

**Please submit ONE DOCUMENT Electronically (PDF format in color) on the NORC** [**website**](http://norcfunding.pbrc.edu)

# Letter of Intent

A letter of intent is required initially to ensure the eligibility and appropriateness of the research topic and to provide a rough estimate of the budget.

**Letter of Intent Guidelines:**

* One page maximum including the following:
* Project title, Principal Investigator and if applicable institutional and inter-institutional collaborations.
* General description of intended work including a statement of intended use of [NORC scientific core](https://www.pbrc.edu/research-and-faculty/centers-and-institutes/nutrition-obesity-research-center/core-services/)s or NORC Biorepository data and/or biospecimens.
* Estimated budget
* If applicable, name of collaborative mentor.
* A strong letter of commitment of retention from the Chairman or Dean for applicants from other Louisiana institutions.
* Senior postdoctoral fellows who have been part of the institution for at least 1.5 years at the time of the award should include a Letter of Support from the mentor or institutional official documenting institutional commitment with potential for a full faculty position.
* [NIH Biosketch](https://grants.nih.gov/grants/forms/biosketch.htm)

Applications should emphasize a **high level of innovation and scientific rigor** and not represent a continuation of an existing prior direction of research. Applicants are expected to demonstrate (i) a **strong scientific premise**, and (ii) how that premise scientifically relates to and advances the theme(s) of the Pennington Louisiana NORC. **Innovation and scientific premise will be deemed more important than preliminary data and experimental minutiae of the proposed project.** Finally, applicants are expected to clearly explain how successful completion of the project will advance their science, and how outcomes of the project will support a future grant application. This includes (but is not limited to) determination of effect size and variation so that power calculations for a future grant proposal can be performed, etc.

**Invitation to Present:**

**Selected investigators will be invited to give a brief presentation to the NORC executive committee on March 24. The idea is to provide initial feedback and to ensure a connection with appropriate NORC core directors. A 5 minute presentation should cover:**

**Significance**

* Does the project address an important problem or a critical barrier to progress in the field?
* If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
* How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

**Innovation**

* Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?

**Investigator**

* Are the PI(s), collaborators, and mentors well suited to the project?

**Approach**

* Is the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
* Scientific rigor: is the planned study design, methods, and statistical approaches likely to generate high quality data worthy of publication or for use as preliminary data in a future grant application?

**Feasibility**

* Is the estimated budget sufficient to cover all project costs? If not, what other support is promised?
* Is the research feasible within the allotted time frame?
* **Only investigators who receive approval following their presentation will be eligible to submit a full application.**
* **The availability of data and/or biospecimens for the proposed research aims must be confirmed by Pennington/Louisiana NORC administrators before investigators are eligible to submit a full application.**

**Format of Application**:

**The application packet must include the following (Applicants are required to use the NIH 398 forms found** [**here**](https://grants.nih.gov/grants/funding/phs398/phs398.html)**.**

1. [NIH Face Page](https://grants.nih.gov/grants/funding/phs398/phs398.html)  - Please list the Principal Investigator’s (PI) name on the top right-hand corner of every page of the application.
2. [NIH Budget page](https://grants.nih.gov/grants/funding/phs398/phs398.html) (Form Page 4 and 5) + 1 page Budget Justification
* When completing the budget page, please refer to the list of expenditures allowed and not allowed included in these instructions.
* Although facilities and administrative costs are allowed under the terms of the prime award, it is our belief that these funds should be used in the spirit intended, i.e., direct costs in support of this project.  **It is hoped that for an award of this type, your institution will be willing to forego the facilities and administrative costs and consider these costs as matching funds for your project.** This provision should be addressed in your letter of support or in a separate letter of support from your grants’ office to this effect.
* *NOTE: Clinical protocols MUST be budgeted through the standard procedures. Contact your Sponsored Projects Office for details.* ***Indirect costs for non-Pennington Institutions are strongly discouraged.***
1. [NIH Biographical Sketch](https://grants.nih.gov/grants/forms/biosketch.htm) including “Other support” if currently independently funded. Include NIH Biographical Sketch from the mentor if applicable.

4. **Research plan** (4-page maximum including references, Arial 11, single-spaced, .5-inch margins).

* 1. **Specific Aims** - State concisely the hypothesis to be tested and the specific aim(s) to be achieved during the grant period. The aims must be reasonable to achieve during the one-year period of the grant.
	2. **Significance and Innovation** - This section must contain a clear explanation of the relevance of the proposed project to nutrition and/or obesity. It will be a key factor (in addition to scientific merit) influencing whether an award will be made. State the relevance of the proposed project to basic or clinical research focused on the prevention and control of chronic diseases. Discuss the use of one or more [NORC Scientific Cores.](https://www.pbrc.edu/research-and-faculty/centers-and-institutes/nutrition-obesity-research-center/core-services/)
	3. **Preliminary Data** (if applicable) - Discuss the pertinent research findings that will help to establish the experience and competence of your project. Note that preliminary data from the lab of the applicant is not a requirement for P&F awards.
	4. **Research Design, Methods and Scientific Rigor** - Concisely present your experimental design and the methods to accomplish your specific aims. Also indicate how the results will be interpreted and how they will lead to future investigations. Well-known methods and standard procedures may be described very briefly or referenced, but novel experimental approaches should be outlined in more detail. This section should represent the bulk of the application.
	5. **Relevance of the Proposed Project to the theme of nutrition/obesity and metabolic health** - (see “Areas of research” above).
	6. If relevant, **the role of the mentor in the design and execution of the proposed research**
	7. **Description of how the results of this study will lead to future investigations/grant applications** - Assuming this P&F grant has a positive outcome, explain in detail how the results obtained will serve as the basis for an application for major research funding for NIH or other national granting agencies. *Simply stating that the results obtained will be used to apply for a grant (or other words to that effect) is insufficient.*
	8. **References.**
	9. **Appendix** - additional materials required.
	+ Letters of support
	+ If the project involves a sponsor, a consultant or a mentor, this individual must write a letter of support for the application and clarify any potential overlap between their support and the subject of the proposal.
	+ Regulatory Approvals for the proposed project should be in process with a protocol and ICF ready for submission at the time of application:

Projection of Human Subjects (if applicable): Institutional Review Board (IRB) approval is not required at the submission stage for a pilot grant. However, we require documentation showing your protocol and informed consent form have been prepared and ready to submit to IRB. As per directions from NIDDK, funds will not be available until the appropriate approvals have been received.

Vertebrate Animals (if applicable): Institutional Animal Care and Use Committee (IACUC) approval is not required at the submission stage for a pilot grant. However, if you are selected as an awardee, you must submit the required paperwork to the IACUC. Funds will not be available until the appropriate approvals have been received.

* + Evidence of available data/samples from the NORC repository (if applicable)

**Additional Instructions:**

If applicable, how your study may utilize and/or contribute to the[NORC biorepository](https://my.pbrc.edu/NORC/NORCRepository/Landing) for clinical samples.

#### Allocation and Expenditure of Funds:

Testing available at the NORC Cores is provided; however, supplies (when applicable) for the testing must be budgeted.

**Expenditures Allowed:**

* Limited technical staff salary support (do not request more than 25% salary for a research associate)
* Research supplies and animal maintenance
* Equipment costs less than $3,000.
* Special fees (pathology, photography, etc.)
* Supplies
* We want to encourage the use of next generation sequencing (Dr. David Burk & Dr. Sujoy Ghosh for details)
* We also encourage the use of spatial assessment of gene expression (Dr. David Burk and Dr. Sujoy Ghosh for details)

**Expenditures NOT Allowed:**

* Principal Investigator, or Co-Investigator, or Mentor salary support
* Secretarial/administrative personnel salary support
* Office equipment and supplies
* Computers
* Tuition
* Domestic or Foreign Travel
* Publication costs, including reprints
* Dues and membership fees in scientific societies
* Purchasing and binding of periodicals and books
* Honoraria and travel expenses for visiting lecturers
* Rental of office or laboratory space
* Construction or building maintenance
* Recruiting and relocation expense
* Facility and Administrative (indirect) costs are strongly discouraged.(see #2 in the Format Application Section above)

**Scoring Metric**

Applications will be scored using the new NIH criterion (effective January 25, 2025):

Factor 1: Importance of Research (Significance, Innovation; scored 1-9)

Factor 2: Rigor and Feasibility (Approach, including Inclusion and Clinical Trial Study Timeline; scored 1-9)

Factor 3: Expertise and Resources (Investigators, Environment; no individual score but considered in overall impact)

Other score driving factors include the likelihood of successful execution within the funding constraints (cost and time), potential for future funding, available mentoring, and other Faculty/Institutional support.

Please check our NORC [website](https://www.pbrc.edu/research-and-faculty/centers-and-institutes/nutrition-obesity-research-center/pf-grants/) or contact Jacqueline Fox (NORC Executive Secretary) at 225-763-2686 or jacqueline.fox@pbrc.edu if you have questions about the P&F application process. Directors of the NORC Cores are available for consultation, regarding study design and procedures/core services available: Cores (Human Phenotyping - Corby Martin or Ursula White, Molecular Mechanisms – David Burk &/or Sujoy Ghosh, and Animal Models – Bob Kesterson)

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| RESPONSIBILITIES OFP&F PROGRAM AWARDEES* 1. All awardees must have appropriate institutional regulatory approvals before funds will be released. (Human Research- IRB approval, Animal Studies - IACUC approval).

**HUMAN RESEARCH REQUIREMENTS FOR NIH:** • Data and safety monitoring plan (DSMP) • Milestones • Documentation of IRB approval • Participant recruitment and retention plan and monitoring • Plan for dissemination of research results **In addition, all NORC P&F-supported projects including non-exempt human subjects****research are required to:** • Submit planned enrollment/inclusion data in the Human Subjects System (HSS) • Register all clinical trials in clinicaltrials.gov and deposit the results according to clinicaltrials.gov regulations * 1. Awardees are required to submit progress reports twice a year – at the midterm and at the conclusion of the grant period. You will be notified when these reports are due. All reports must be sent to the NORC Administrator.
	2. Awardees are expected to present their research at the NORC Executive Committee meeting tbd.
	3. Awardees are required to acknowledge the Pennington/Louisiana NORC grant in all publications, posters, press releases, proposals, abstracts, and/or presentations that are produced as a result of P&F funding. Please use the following acknowledgement: “Research reported in this publication was supported by the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health under Award Number P30DK072476. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”
	4. If you are awarded a grant based on preliminary data obtained from your pilot study, please notify the NORC administrator, Jacqueline Fox immediately.
	5. After completing the project, awardees will be requested to continue to report any new progress (grants, publications, etc.) resulting from preliminary data obtained from their P&F award. The Pennington/Louisiana NORC is required to report all updates from P&F funding to the NIH to help the NIH evaluate the effectiveness and productivity of the Center. Please send all project updates to Jacqueline Fox.
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