

North Carolina Diabetes Research Center (NCDRC) Pilot Grants Request for Applications 2020

Letter of Intent Deadline: 11:59 p.m. ET, May 1, 2020

The goal of the North Carolina Diabetes Research Center (NCDRC) is to increase the impact of the already important diabetes research ongoing at Duke University, North Carolina Agricultural and Technical State University (NC A&T), the University of North Carolina at Chapel Hill (UNC), and Wake Forest School of Medicine (WF). Each has rich resources and outstanding investigators, and the NCDRC represents a timely opportunity to enhance interactions among these research communities, and expand unique capabilities at each site to their neighboring campuses. The mission of the NCDRC is to provide investigators, both established in or new to diabetes research, with access to powerful research technologies to enhance the impact of their work, as well as to connect investigators with collaborators, both at intra- and inter-institutional levels, to broaden the scope of their projects.

I. Purpose

This Pilot and Feasibility (P&F) program is designed to encourage and facilitate novel basic clinical and translational research. Projects must demonstrate a clear path to subsequent grant support, translation to clinical programs, new company formation, licensing, not-for-profit partnering, or other channels. **Projects must have a clear diabetes focus.** Collaborative projects with investigators from other NCDRC institutions will be given priority for funding, as will proposals that make meaningful use of Core facilities at one of the following institutions:

- Duke metabolomics (david.d'alessio@duke.edu)
- Wake Forest proteomics/genomics (molivier@wakehealth.edu)
- UNC advanced clinical studies methods (john_buse@med.unc.edu)
- Novel animal models (kkavanag@wakehealth.edu)

These pilot grant awards are not meant as bridge funding or as supplementary funding for existing projects.

II. Key Dates

Date	Detail
05/01/2020, 11:59 pm	Letter of Intent (LOI) Deadline
05/15/2020	Investigators Invited for Full Application
06/12/2020, 11:59 pm	Full Application Deadline
07/01/2020	Project Start Date
06/30/2022	Project End Date

III. Eligibility

To be considered eligible to apply for P&F funding, independent investigators holding faculty appointments at the participating NCDRC institutions have to fit into one of the following four categories:

- New investigators that have no current or past R01-level NIH research support, or equivalent VA or Foundation support, as a PD/PI, as per the NIH policy on Early Career Investigators.
- Established investigators new to diabetes research: these investigators have to demonstrate that they have not had previous funding/work in diabetes and provide a letter of intent explaining how they plan to apply their expertise to a problem related to diabetes (basic mechanisms of diabetes or diabetes-related complications or co-morbidities).
- Established investigators in diabetes: a subset of awards will be allocated to investigators already well-established in the diabetes field and that propose to test innovative ideas embodying a clear departure from ongoing research interests.
- Research method or technology advancement: investigators developing new research techniques or novel technologies that could be used in a DRC Core facility will also be considered for P&F funding.

Note:

- More than one proposal may be submitted per faculty member acting as PI, but the faculty member is only eligible to receive one award as PI during a given funding cycle.

- Interested investigators who need assistance identifying collaborators should contact leadership at the individual institutions:

Duke:

- Scholars@Duke, scholars@duke.edu
- Duke CTSI, ctsifunding@duke.edu
- David D'Alessio, david.d'alessio@duke.edu

NC A&T:

- Robert Newman, rhnewman@ncat.edu
- Elimelda Ongerer, eonger@ncat.edu

UNC:

- Reach NC, <https://uncch.pure.elsevier.com/en/>
- NC TraCS, mblister@med.unc.edu
- John Buse, john_buse@med.unc.edu

WF:

- Wake CTSI, ctsi@wakehealth.edu
- Donald McClain, dmccclain@wakehealth.edu

IV. Funding

Up to three projects will be funded (*the final budget for the NCDRC is still pending*). Successful pilots will receive up to \$50,000 in direct costs per year for two years. All projects must meet the above specifications outlined under “Purpose” and “Eligibility”. Final project budgets will be based on a complete review of the submitted budget and budget justification. See “Budget Guidelines” below for more details. All funds are to be spent within a two-year project period.

V. Selection Process and Review Criteria

Applications will be reviewed by a joint Duke / NC A&T / UNC / WF Study Section composed of three faculty from each institution in addition to four experts from outside. Review criteria will include:

- Focus on diabetes
- Significance of the work
- Novelty/Innovation of the research idea
- Use of services and resources of the NCDRC
- Formation of new partnerships for advancing diabetes research, especially across NCDRC sites.
- Relevance of the proposed study to translational research while maintaining a goal to support as many basic as clinical investigators
- Potential for the project to lead to future external funding or to a commercialization opportunity
- Soundness of the proposed methods
- If a senior-level PI, whether the application represents a new research direction
- Feasibility of accomplishing the stated project goals within the two-year project period
- Level of community engagement (if applicable)

VII. Letter of Intent Application Procedure

- Applicants should submit an initial Letter of Intent (LOI) (3 pages maximum). The LOI will assist in providing initial feedback to ensure proposed projects are scientifically aligned with the mission of the NCDRC.
- To apply, visit: [Diabetes Research Collaborative Pilot Grants LOI](#)
- The Letter of Intent should include:
 - A brief abstract, including specific aims
 - A clear statement addressing the diabetes focus of the project
 - A list of study team members and their institution for the proposed project
 - A brief justification of study team members’ role and contribution to the project
- **Deadline is 5/1/20**
- Invitations to apply for a full application will be sent by 5/15/20.
- For questions, please contact Brittney Jackson at britjack@wakehealth.edu.

VII. Full Application Procedure

Applicants will enter general project information via the web-based form.

- Project Title, Brief Description, and Amount Requested
- Investigator Information: Name, rank, department and institution
- General Project Information: Applicants will be asked to answer general questions regarding the project (e.g. clinical need, IRB, IACUC, etc.).

Proposal sections will be uploaded as individual PDF files. The application sections are:

- A. Scientific Abstract: The abstract summary of the proposal for use by review committee members (250 word maximum).
- B. Research Plan: The Research Plan should follow the standard NIH format: Specific Aims, Significance, Innovation, and Approach. Include where applicable clear evidence of how the proposal meets the review criteria. (5-page limit, including tables and figures. References do not count toward the 5-page limit; single line spacing, font no smaller than Arial 11, 1-inch margins.)
- C. Budget form with Budget Justification: The Excel budget worksheet should be completed along with a budget justification and uploaded within the application. The Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested.
- D. Proposal Timeline
- E. Human and/or Animal Subjects: Institutional Review Board (IRB) or Institutional Animal Care & Use Committee (IACUC) approval is not required prior to submission but will be required prior to funding. Briefly describe any human and/or animal subject issues. If human subjects are involved, provide a description of their involvement and characteristics, specific risks to subjects who participate, and protection against those risks. Describe the sources of materials that will be obtained from human subjects as part of their study participation. Provide assurance that the project will be reviewed and approved by the institutional IRB and comply with HIPAA. If vertebrate animals are to be used, provide a description of the proposed use of the animals in the work outlined and procedures for ensuring that discomfort, distress, pain and injury will be limited. Projects involving animal subjects must be reviewed and approved by an institutional IACUC. (no page limit)
- F. NIH Biosketches for key members of the research team (as a single PDF)

VII. Budget Guidelines

Please note the following during budget preparation:

- The budget period is for two years beginning July 1, 2020 and ending no later than June 30, 2022.
- Up to \$50,000 in direct costs may be requested.
- Funding will not be available until applicable IRB/IACUC documentation is provided.
- Grant funds may be budgeted for:
 - Research support personnel
 - No more than \$10,000 in summer salary support for the PI or faculty collaborators
 - Travel necessary to perform the research
 - Small equipment, research supplies and core lab costs
 - Other purposes deemed necessary for the successful execution of the proposed project
- Grant funds **may not** be budgeted for:
 - Salary support for the PI or faculty collaborators, outside of the \$10,000 mentioned above
 - Effort for post-doctoral trainees or fellows on training grant equivalents
 - Capital equipment
 - Office supplies or communication costs, including printing and postage
 - Meals or travel, including to conferences, except as required to collect data
 - Professional education or training
 - Computers or audiovisual equipment
 - Cell phones
 - Manuscript preparation and submission
 - Indirect costs
 - Subcontracts to other institutions
 - Foreign components, as defined in the NIH Grants Policy Statement

- Awarded funds must be used to conduct the work proposed. The NCDRC reserves the right to revoke funding in the event it is determined that funds were not spent in accordance with the approved proposal. The general criteria for determining allowable direct costs on federally-sponsored projects is set forth in **2 CFR Part 200: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards** (The Uniform Guidance). The **Duke General Accounting Procedure** (GAP) 200.320 is a resource to determine whether or not a particular cost item would be considered an allowable direct cost for budgeting and/or charging on a federally sponsored project.

VIII. Terms of the Award

A. Approvals Required Prior to Funding Start Date

- Prior to receiving funds, research involving human subjects must have appropriate approvals from the IRB. If the research includes animals, the appropriate IACUC animal research forms must also be approved before the project's start date. Either an IRB approval letter or an IRB response to a "Determination Whether Research or Similar Activities Require IRB Approval" must be submitted prior to funds being released. Human subjects or animal research must be reviewed in accordance with the university's general assurances and HIPAA. In addition, if the research involves human subjects, all personnel named on the budget page must have certification of training in the protection of human subjects prior to the start of the grant period.
- Failure to submit documents in the requested timeframe may result in cancellation of funding.

B. Project Execution

- Project investigators will submit a 1-page progress report annually to the Director of the P&F Program. Less formal assessments will be conducted every 4 months to ensure that a project is still on track and that funds are being expended in a timely manner.
- All publications that are the direct result of this funding must reference: "Research reported in this publication was supported by the North Carolina Diabetes Research Center." Publications must also be registered in PubMed Central. After your publication is accepted, [click here](#) for a guide to complying with the NIH Public Access Policy.

C. Post-Award Reporting

The NCDRC will contact investigators annually to determine if any milestones have been achieved as a result of this award. Examples include:

- Abstracts/presentations, manuscripts, published guidelines
- Follow-on funding (e.g., grants, SBIR/STTR, angel and venture capital investment)
- Milestones achieved in animal models, manufacturing and toxicity campaigns
- Regulatory meetings and filings (e.g., 510K, IDE, IND, BLA, NDA)
- Initiation of appropriate clinical studies
- Improved diagnosis or treatment of disease
- Implementation in clinical practice and community
- Translation of models to other geographical areas
- Translation of models to other therapeutic areas
- Clinical outcomes in practice and communities
- Agreements with partners and strategic collaborators to translate more broadly
- Commercialization (e.g. new intellectual property, patent applications, license, commercial partnerships, start-up company)
- Direct-to-consumer interactions (e.g. apps)

When requested, all awardees will be expected to provide updates of publications and other translational units that originated from the award.

Awardees and applicants are expected to serve as reviewers for future NCDRC funding opportunities.

ADDITIONAL CONTACT INFORMATION

For additional information on this funding opportunity, please contact Brittney Jackson at britjack@wakehealth.edu.