

North Carolina Diabetes Research Center (NCDRC) Pilot Grants Request for Applications 2021

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 one of the following Core facilities:

- Duke Metabolomics (david.d'alessio@duke.edu)
- WF Proteomics/Genomics (molivier@wakehealth.edu)
- UNC Advanced Clinical Studies Methods (john_buse@med.unc.edu)

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

II. Key Dates

Date	Detail
12/16/2020, 11:59 pm (ET)	Letter of Intent (LOI) Deadline
01/08/2021	Invite for Full Application
02/05/2021, 11:59 pm (ET)	Full Application Deadline
03/05/2021	Selection of Awardees
04/01/2021	Project Start Date
03/31/2023	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. Specific to the LOI, these investigators have to demonstrate that they have not had previous funding/work in diabetes and describe how they will apply their expertise to a problem related to diabetes (basic mechanisms of diabetes, diabetes-related complications, co-morbidities, etc.).
- 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 methods 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:**
 - WF CTSI, ctsi@wakehealth.edu
 - Donald McClain, dmccclain@wakehealth.edu

IV. Funding

Up to three projects will be funded. Successful pilots will receive up to \$50,000 in direct costs per year for two years (\$100,000 total). 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 at least three faculty from each institution in addition to at least 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)

VI. Letter of Intent (LOI) Application Procedure

- Applicants should submit a Letter of Intent (LOI).
- The Letter of Intent (2 pages max) should include:
 - A brief abstract, including specific aims
 - A clear statement addressing the diabetes focus of the project.
 - A list of study team members, their institution and a brief justification of role and contribution for the proposed project. All team members should have agreed to participate.
- To apply, visit the ePilot application: <https://redcap.wakehealth.edu/redcap/surveys/?s=RAWJLWJHxD>
- **Deadline is 12/16/20 at 11:59 pm (ET)**
- For questions, please contact Brittney Jackson at britjack@wakehealth.edu

Review Criteria and Process for Letters of Intent

1. An Administrative Review will be completed to verify all required components were submitted and formatting guidelines followed (e.g. does not exceed page limit).
2. Letters of Intent that pass the Administrative Review are reviewed by the NCDRC Leadership. Reviewers at this stage will be looking for whether proposed projects have a diabetes focus and meet eligibility requirements to ensure the project is responsive to the RFA.
3. An invitation to apply for a full application, or notification if you are not selected, will be communicated via e-mail by 01/08/2021.

VII. Full Application Procedure

Investigators invited to apply will receive an e-mail by 01/08/21 with a link to submit a full application by **02/05/21 at 11:59 pm (ET)**. **Applications received after 11:59 pm (ET) on 02/05/21 will not be reviewed.** Application instructions are included in the ePilot system and summarized below.

Format Specifications

- Arial font and no smaller than 11 point
- 1-inch margins (sides, top, and bottom)
- Single Line Spacing

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

- **Scientific Abstract:** The abstract summary of the proposal for use by review committee members (250 word maximum).
- **Research Plan** (5 pages max, all items below are required components)
 - a. Specific Aims
 - b. Research Plan
 - i. Significance
 - ii. Innovation
 - iii. Approach
 - iv. Study Team
 - c. Include, where applicable, clear evidence of how the proposal meets the review criteria.
- **References** (do not count toward the 5-page limit)
- **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 (1 page maximum) should include sufficient detail for reviewers to assess whether appropriate resources have been requested.
- **Proposal Timeline**
- **Human Subjects Information**

Address the following if the project **involves human subjects**.

 - a. IRB Approval Status. IRB approval will be required (as 'just in time' information) for implementation of projects with human subjects.
 - b. Clinical Trials Classification Questions
 - c. Protection of Human Subjects
 - Needs to clearly describe risk, protections, benefits, and importance of the knowledge to be gained by the revised or new activities as discussed in Part II of NIH competing application instructions
 - d. Inclusion Plans for Women, Minorities, and Children, if applicable
 - e. Recruitment and Retention Plan
 - f. Targeted Enrollment Table (using Appendix I)
 - g. Data and Safety Monitoring Plan (DSMP) and Board (DSMB), if applicable
- **Live Vertebrates Information**

Address the following if the project **involves live vertebrates**.

- a. IACUC Approval Status. IACUC approval will be required (as ‘just in time’ information) for implementation of projects with live vertebrate animals.
- **NIH Biosketches** for key members of the research team (as a single PDF)

Review Criteria and Process for Full Proposals

1. An Administrative Review will be completed to verify all required components were submitted and formatting guidelines followed. **Applications that do not comply with guidelines will be automatically disqualified and will not be considered for review.**
2. Proposals that pass the Administrative Review are peer-reviewed by the NCDRC Scientific Review Panel using NIH review criteria and scoring. Budgets will be reviewed by both NCDRC Administrators and NCDRC Scientific Review Panel for appropriateness.
3. Final award approval will be at the recommendation of NCDRC Leadership.

Reviewers will score applications following the NIH scoring system, i.e. 9-point rating scale (1 = exceptional; 9 = poor):

1. Significance of the problem to be addressed
2. Innovation of the proposed solutions
3. Methodological rigor and feasibility, with clear milestones
4. Strengths and breadth (interdisciplinary nature) of the investigative team
5. Generalizability: Likelihood the innovation will be broadly applicable and impact translational research or delivery of care
6. A reporting plan, whether the study yields positive or negative results
7. The likelihood that the investment will lead to external funding, publication, or a licensable innovation; early-career faculty involvement, race/gender inclusiveness of the research team; and inclusion of women, minorities, older adults, and children as potential study participants.

VIII. Budget Guidelines

Please note the following during budget preparation:

- The budget period is for two years beginning April 1, 2021 and ending no later than March 31, 2023.
- Up to \$50,000 per year 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:
 - Summer salary support for the PI or faculty collaborators, outside of the \$10,000 mentioned above
 - Effort for post-doctoral trainees or fellows on training grants or 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.

IX. Terms of the Award

A. Approvals Required Prior to Funding Start Date

- Prior to receiving funds, research involving human subjects must have appropriate approval from the IRB. Either an IRB approval letter or an IRB response to a “Determination Whether Research or Similar Activities Require IRB Approval” must be submitted to the NCDRC prior to funds being released. Human subjects must be reviewed in accordance with the institution’s general assurances and HIPAA. All key personnel must have certification of training in the protection of human subjects prior to the start of the grant period.
- Research involving human subjects must also have approval from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).
- Prior to receiving funds, research involving live vertebrates must have appropriate approvals from IACUC. Either an IACUC approval letter or documentation on why activity does not require IACUC approval must be submitted to the NCDRC prior to funds being released.
- 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

Planned Enrollment Report

This report format should NOT be used for collecting data from study participants.

Study Title:

Domestic/Foreign: Domestic

Comments:

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native					0
Asian					0
Native Hawaiian or Other Pacific Islander					0
Black or African American					0
White					0
More Than One Race					0
Total	0	0	0	0	0