

NC Diabetes Research Collaborative Pilot Grants - Request for Applications 2018-2019

Letter of Intent Deadline: 11:59 p.m. ET, April 02, 2018

Duke University, UNC-Chapel Hill (UNC-CH), Wake Forest Baptist Medical Center and North Carolina A&T State University are interested in promoting inter-institutional collaborations in diabetes research as part of the new North Carolina Diabetes Research Center (NCDRC). Pilot funds are now available for eligible new investigator teams.

I. Purpose

This pilot program is designed to encourage and facilitate novel basic clinical and translational research. Projects must demonstrate a clear path to subsequent grant support, new company formation, licensing, not-for-profit partnering, or other channels. Projects must **have a clear diabetes focus** and involve **co-Principal Investigators at a minimum of two of the four institutions**. Additional priority will be made for 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

- Letter of Intent Due 04/02/18
- Full application invitation 04/13/18
- Full application due 05/11/18
- Funding Period: The budget period is for 12 months beginning between July 1, 2018 and ending no later than June 30, 2019.

III. Eligibility

- Proposed projects must involve a lead investigator from at least two of the four participating institutions. Proposals are encouraged from new teams of investigators from different disciplines. Applicants at each institution must have a full-time faculty appointment.
- 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:

Duke contact:

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

UNC-CH contact:

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

Wake Forest contact:

- ctsi@wakehealth.edu
- Donald McClain dmclain@wakehealth.edu

NC A&T contact:

- Elimelda Onger eonger@ncat.edu
- Meriel Parker mparker2@ncat.edu

IV. Funding

The research activities at each participating institution will be funded by that institution. Each institution will contribute up to \$25,000 in direct costs, with a limit of a total of up to \$100,000 per collaborative project if all 4 institutions are involved.

V. Selection Process and Review Criteria

Applications will be reviewed by a joint Duke/UNC/Wake/NCA&T Study Section. Review criteria will include:

- Significance of the work
- Novelty/innovation of the research idea
- Relevance of the proposed study to translational diabetes research
- Applicants are a new multidisciplinary team who have not previously published or been awarded grants together in this area of research OR the work represents a significant change of research direction for all PIs
- Potential for the project to lead to future external funding or to a commercialization opportunity
- Soundness of the proposed methods
- Feasibility of accomplishing the stated project goals within the one-year project period

VI. LOI 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 goals of the collaborative.
- To apply visit [Diabetes Research Collaborative Pilot Grants LOI](#)
- The application should include:
 - A brief abstract, including specific aims
 - A clear statement addressing the diabetes focus of the project
 - A list of study team members (including lead investigators from partner sites) for the proposed project
 - A brief justification of study team members' role and contribution to the project
- **Deadline is 04/02/18**
- Invitations to apply for a full application will be sent 04/13/18
- For questions, please contact Jennifer Aiken at jraiken@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 and department.
- General Project Information: Applicants will be asked to answer general questions regarding the project (e.g. clinical need, IRB, IACUC, etc.).

Proposal sections (except the Abstract) 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 with Budget Justification using PHS 398 Form Pages 4 and 5 (combined into a single PDF without a page limit). Section VI below provides more detail on budget preparation. The Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested. Each PI/institution's budget should be prepared on separate form pages but submitted together as a single PDF.
- 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 12 months beginning between July 1, 2018 and ending no later than June 30, 2019.
- Up to \$25,000 in direct costs at each institution may be requested and the amount requested from each must be equal as funds will not be subcontracted between the institutions.
- Funding will not be available until applicable IRB/IACUC documentation is provided.
- Grant funds may be budgeted for:
 - Research support personnel
 - Travel necessary to perform the research
 - Small equipment, research supplies and core lab costs, or
 - 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
 - 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, or
 - Foreign components, as defined in the NIH Grants Policy Statement
- Awarded funds must be used to conduct the work proposed. All direct charges to this award must adhere to federal regulations and requirements regarding the use of CTSA funds. Participating institutions reserve 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

- NCDRC staff will work closely with funded teams throughout the grant period to monitor progress and, when necessary, provide assistance. A six-month interim progress report and a final progress report will be required. We expect PIs to report over the lifetime of the work the outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations and patents.
- 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 Jennifer Aiken at jraiken@wakehealth.edu.