2020 REQUEST FOR PROPOSALS (RFP)

The National Diabetes and Research Institute (NDORI), in affiliation with Cleveland Clinic's Endocrinology & Metabolism Institute (EMI) is seeking RFPs for basic type 2 diabetes research.

BRIEF DESCRIPTION: Using an evidence-based approach to build our healthcare system delivery model, NDORI and EMI has the unique ability to study, analyze, and report the systems and processes of patient care. This RFP plans to put that strength to work, in the basic science field of addressing, in an innovative fashion, disease mechanisms involved in the onset and progression of obesity and type 2 diabetes.

Purpose -- to apply basic science rigor to study ways to cure or put diabetes and obesity into remission.

Concept Development – NDORI foundational aims are to cure obesity and diabetes. This study will allow innovative basic fundamental research approaches to investigate ways to seek a cure for diabetes with plans to publish findings in peer-reviewed journals, develop enduring materials, and showcase presentations.

AMOUNT AND DURATION OF FUNDING: NDORI will provide one research grant of $300,000 per year (total costs) for innovative basic research projects addressing type 2 diabetes, with the possibility for renewal and additional funding in Year 2. Availability and commitment of funds are required prior to review by the NDORI Research Advisory Committee (RAC). Funding for Year 2 will be contingent on substantial progress reports from the first year and may result in additional funding up to $300,000. Carry forward funding from one year to the next will require pre-approval.

APPLICATION PROCESS: Applicants should submit a proposal of the planned research with a detailed budget (see requirements later in the document). NDORI's RAC will review the applications using the criteria of scientific quality and responsiveness to NDORI's purpose.

ELIGIBILITY: Applicants must be NDORI stakeholders and hold an MD, PhD, DMD, DO, PharmD or an equivalent health-or science-related degree

TIMETABLE:

Grant Notification sent on Nov 15th to NDORI key stakeholders - Cleveland Clinic Basic Research Institutes, Keesler Medical Center, LSU and William Carey and posted on NDORI website.

January 15, 2019 - Applications due
Feb 15, 2020 - Finalist notifications determined
March 4, 2020 – Award announced at the VJ Canizaro, MD, Health Summit
April 1, 2020 - Funding begins

In affiliation with

Cleveland Clinic
Endocrinology and Metabolism Institute

THE NATIONAL DIABETES
& OBESITY RESEARCH INSTITUTE
AT TRADITION

SUBMISSIONS: Applications should be submitted electronically via email to ATTN: NDORI's Executive Director Stephan L. Farrow, MD, (email Emily Foret at eforet@ndori.org) and ATTN: NDORI's Executive Medical Director Bartolome Burguera, MD, (email burgueb@ccf.org). Application submissions that are incomplete or do not adhere to section page limits will be administratively disapproved. Please see checklist at the end of this document.

REVIEW CRITERIA: The review of applications by the NDORI RAC will focus on the quality of the application and alignment to the goal of addressing disease mechanisms for onset and early progression of obesity/type 2 diabetes. NDORI's goal is designed to foster innovation in basic science and will be awarded based on the proposed research challenges, existing paradigms or developing new, innovative mechanistic studies, products, methods or technologies for curing diabetes. Emphasis will be placed on applications that seek future funding beyond this grant, such as performing preliminary work and facilitating collaboration for innovative ongoing research. In addition, review criteria will include the significance of the problem to be addressed by the research; the potential impact of the research on the concepts or methods driving the field; the likelihood that the research will be successful; the approach, i.e., the conceptual framework, design, methods and analyses, to be used to achieve the aims; and the track record or potential of the investigator(s) to move the innovation forward toward commercialization (if applicable).

PROGRESS AND RENEWAL: A progress report will be due at the beginning of the sixth month of the 1st year of funding. The progress report should include a summary of the progress to date, including a summary of first year expenditures, milestones (for Concept Development projects) and a budget for the second year if on plan. Any problems encountered during analysis or studies should be noted along with plans for rectifying them. The progress report should also include a list of all proposals, abstracts, enduring materials and publications that have resulted from the topic of research, a list of related extramural funding submitted and received, and a list of any intellectual property generated (including invention disclosures, submitted and received patents, licenses, and any new companies formed). Continuation of funding for the second year will be determined by the RAC and/or Steering Committee. Upon completion of the project, a final progress report and presentation to leadership will be due within 45 days of award termination.

ETHICS: All requests must conform to prevailing ethical standards for medical research and must have been approved by the IRB, as applicable, before beginning the research.

OTHER FUNDING: This funding may not be used to replace support for projects that are already funded from other sources, but can leverage support for research efforts with existing funding.

NDORI 2020 RFP APPLICATION

Please submit a PDF of the completed and signed application by January 15, 2020 emailed to Emily Foret at eforet@ndori.org and Bartolome Burguera, MD at burgueb@ccf.org

Basic Research Project Name:

1) Research Plan

Complete a detailed plan of the proposed research following the outline below. Figures and tables must be included within the maximum page limits within each section of the Research Plan. Applications that do not conform to these guidelines or exceed the maximum page limits within each section will be administratively disapproved.

The overall proposal should be kept as brief as possible while still presenting the complete research plan. As a panel of experts in the field will review proposals, established methods may be referred to by reference rather than described in detail in the proposal. New methodology or novel approaches should be described in detail. In general, the scope of the proposal should match the program budget.

The following format must be used for the Research Plan:

a) Specific Aims (1-page maximum; 1-figure maximum)

Provide an overview of the proposed project, including a high-level summary of the problem, relevance to the disease state and theoretical framework. Concisely state the goals of the work and summarize the expected outcome(s).

b) Significance and Innovation (1-page maximum)

Explain the importance of the problem or barrier to progress in the field of diabetes research addressed by the project, and the necessity of the proposed work to the development of new knowledge in this research area. Describe how the expected results will make a clear and significant contribution to the field of scientific knowledge, technical capabilities and/or clinical practice for people with diabetes.

Describe any novel theoretical concepts or approaches utilized or developed by the proposed work, and any new applications/improvements in methodologies, instrumentation or interventions.

c) Research Approach (8-page maximum)

Describe the overall strategy, methodology and analyses used to accomplish the specific aims of the project, integrating any preliminary data into discussion of the specific aim(s). Discuss any potential pitfalls and outline contingency plans. Particularly if the project is in the early stages of development, address the management of any high-risk aspects of the proposed work and describe strategies to establish feasibility. Figures and tables must be included within the 8-page limit.

2) Open Data and Resource Sharing Plan (1-page maximum)

The data and resource sharing plan must not exceed one page. It must address (1) a brief summary of data outputs and/or resources that the proposed research will generate; (2) anticipated date when data and resources will be shared (no later than 6 months post-publication or 18 months from the award end date); (3) proposed repository for data sharing and (4) justification for why the data and resource sharing plan is strong.

Applicants should also address whether a data-sharing agreement will be required and, if so, provide a brief description of such an agreement (including the criteria for deciding who can receive the data and whether any conditions will be placed on their use). References to data and resource sharing may also be appropriate in other sections of the application.

A 1-page maximum request for waiver may be submitted in place of the Open Data and Resource Sharing plan, in only one of the following categories:

• Human Subject Protection (privacy regulations or consent of research participants)

• Superseding Regulations (laws or institutional policies)

• Intellectual Property (existing IP rights)

3) References (5-page maximum)

The references made in the Research Plan must not exceed five pages and must adhere to all formatting requirements stated on page 13. As applicable, the PI's name must be highlighted on all referenced publications.

4) Manuscripts (limit 2 manuscripts)

Applicants may include manuscripts that describe previous work related to the proposed research. Applicants cannot submit more than two manuscripts per application. Manuscript submissions do not have a page limit and are not required to be published at the time of submission.

5) Budget

An itemized budget must be included. Separate Budget Forms must be included for each individual subcontract. Indirect costs (F&A) shall not exceed 10% of the total budget.

6) Budget Justification

a) Professional Support (PI Salary and Technical Personnel)

List the name, position, organization, role, percent effort and capacity of each professional associated with the project according to the following format:

Jane Smith, PhD, Assistant Professor, Division of Endocrinology, State University, PI Principal Investigator (xx% effort/year) <Describe capacity here>

John Grant, PhD, Assistant Professor, Division of Physiology, University of State, Consultant Collaborating Investigator (xx% effort/year) <Describe capacity here>

Examples of professionals include the following:

• Principal Investigator (PI): The one applicant from the sponsoring institution who is responsible for the project's research design and technical direction. PIs must have a doctorate-level degree (e.g., MD, PhD, DPM, etc.). The American Diabetes Association does not recognize co-PIs.

• Collaborating Investigator: A person who devotes a considerable percent effort toward developing and/or implementing the research project. Collaborating investigators usually have doctorate or other professional degrees.

• Consultant: A person who has an independent role in developing or implementing the research project. Consultants tend to provide separate services that are performed within a certain amount of time or intermittently provide a certain technique and/or analysis for the project. Consultants usually have doctorate or other professional degrees.

• Technical Personnel: Any individuals working on the research project in a scientific or technical capacity. For example, postdoctoral fellows, graduate students, lab technicians, nurses, statisticians, and patient recruiters.

Other Professional: A person who has the qualifications in a specific area, such as biostatisticians, epidemiologists, etc.

Budget Categories:

Provide a detailed budget justification corresponding to each budget category identified in the Budget Form (Supplies, Equipment, and Other Expenses). Categorize purchases by general item (glassware, chemicals, etc.) and include a dollar amount. Animal housing and acquisition costs may be included under "Other Expenses." Include the number of animals and price per animal (if purchased with award funds), and the facility's per-diem animal care rate, if available. Provide further explanation/specific de-tails if animal care costs are unusually large or small.

7) Facilities

Describe the facilities available to you for performing this research at your institution. It is expected that PIs have designated lab space and office space specifically assigned to them.

8) Biographical Sketch (5-page maximum per biosketch)

Required for PI; any personnel included in the budget with a graduate degree or above; and any key professional regardless of whether they receive salary support from the project.

The NIH Biographical Sketch Format is acceptable for this application. Applicants and/or technical personnel who do not have an NIH Biosketch should use the automated NIH SciENcv utility to create one. The SciENcv tool is available through myNCBI at ncbi.nlm.nih.gov/sciencv.

9) Completed, Current and Pending Funding

List the PI's completed, pending and current sources of support, including federal (NIH, VA, NSF, etc.), non-profit, industry, and other.