REQUEST FOR APPLICATIONS

TO: Cancer Center & LEAD faculty

FROM: Linda Cook, PhD, Associate Director, Population Science, CU-Cancer Center
Dana Dabelea, MD, PhD, Director, LEAD Center
Wei Perng, Associate Director, LEAD Center

RE: Joint LEAD Center/CU-Cancer Center Pilot Grant Mechanisms – 2023

DATE: Sept 20, 2023

The University of Colorado (CU) Cancer Center and the Lifecourse Epidemiology of Adiposity and Diabetes (LEAD) Center are interested in promoting innovative and impactful research that addresses the connection between metabolism (diabetes/prediabetes, obesity, metabolic syndrome) and cancer, including shared biological (e.g., inflammation, epigenetic mechanisms, hormones) as well as psychosocial pathways (e.g., body image/compassion, mental health). We seek to fund proposals that have a high likelihood of leading to collaborative NIH or equivalent research funding. We anticipate that the projects will be led by multiple PIs (MPIs) with one faculty PI from each Center. Preference will be given to applications that have an early-stage investigator (ESI) as an MPI. In this context an ESI is defined as someone that has not yet received independent NIH funding. Pilot grant applications that address minoritized racial and ethnic groups, underserved populations, and rural and frontier communities are encouraged. We plan to fund up to two pilot grants for 1 year of funding. Each proposal can request up to $50,000 with justification and will be awarded for a 1-year period from Jan 1\textsuperscript{st}, 2024 – Dec 31\textsuperscript{st}, 2024. The proposed work is expected to be completed within 12 months; extensions will only be considered in extreme circumstances. Recipients are expected to submit competitive national grant proposals within 6 months following the completion of the scope of work proposed in the pilot grant application.

Submit a PDF of your complete application online at:
Joint UCCC-LEAD Center Pilot Project Submission Form

The deadline to submit: 11:59 PM MT November 16, 2023

Funding decisions: announced by early December

Funding period: Jan 1 – Dec 31, 2024
APPLICATION GUIDELINES

Applications must include all sections outlined below. Non-conforming applications will not be reviewed. All sections must maintain at least ½ inch margins; at least single-spaced; and in a font size not less than 11 point.

Applicants must be current or pending members of the CU Cancer Center and the LEAD Center. Cancer Center membership applications and guidelines are found on-line at: https://medschool.cuanschutz.edu/colorado-cancer-center/research/membership-resources. LEAD Center members comprise faculty housed in the LEAD Center or conducting research using LEAD datasets (please contact Wei.Perng@CUAnschutz.edu for questions regarding eligibility as LEAD faculty). Only one proposal per contact PI will be accepted.

1. **Title Page**: Include the title of the project and the name and email address of the Principal Investigator(s) and other Key Personnel.

2. **Project Summary**: Include a summary of the project not to exceed one-half page or 30 lines of single-spaced type. It should consist of a brief description of the objectives, rationale, methods, and expected results.

3. **Budget**: A categorical budget (e.g., Personnel, Materials/Supplies, Other, etc.) request for the project must be provided. The budget request can be up to $50,000 direct costs for one year only. Faculty salary support is not allowed (see #4 regarding allowable salary coverage). Funds will not be provided to pay for standard of care clinical services or other expenses that are reimbursable through insurance. No indirect costs will be funded. We anticipate a start date of Jan 1, 2024.

4. **Budget Justification**: Include a budget justification for all costs. Requests for travel funds or for items of capital equipment (i.e., equipment at or exceeding $5,000 per item) will require detailed justification. This mechanism will not cover PI salary but justifiable staff salary coverage is allowable.

5. **Project Narrative**: Provide a complete but concise description of the project including the following sections (adherence to stated page limits is required):
   - Specific Aims – 1 page or less
   - Research Strategy – 5 pages or less
     - Significance (~1 page)
     - Innovation (~0.5 page)
     - Approach (~4.5 pages)
   
   The Project Narrative should be no more than 6 typed pages. Other than letters of support from appropriate community organizations, appendices will not be accepted or reviewed.

6. **Timeline**: On a separate page, using a GANTT chart (see page 5) or similar visual, provide a timeline for the major activities associated with your specific aims and include a list of key milestones for the project that are relevant to demonstrating progress and planning for future extramural grant submissions.

7. **References**: References should be included and are in addition to the previously outlined page limits.

8. **Biographical sketch(es)**: Include an NIH-style biographical sketch for all key personnel listed on the title page.

**Regulatory Documentation**: If the study involves human subjects, vertebrate animals, or recombinant DNA research, the Principal Investigator must certify that, if a grant is awarded, he/she will adhere to appropriate regulations, including approval of the study by the properly constituted Institutional Review Board, Institutional Animal Care and Use Committee, Protocol Review and Monitoring Committee, and/or Biosafety Committee. **Funds will not be awarded until documentation of all required regulatory approvals are provided.**
**EXAMPLE PROJECTS**

This RFA targets three broad categories of projects that demonstrate high likelihood of leading to new extramural funding. Basic research that falls into one of these categories is acceptable, especially in collaboration with a population scientist. Example topics are provided below. Please email Wei Perng or Linda Cook if you are uncertain about a topic or approach:

1. **Linkage studies that will support new funding.** Studies linking diabetes registries to NCI’s Surveillance, Epidemiology and End Results (SEER) program examining the increased risk of various cancers associated with diabetes/obesity
2. **Secondary analyses that will support new funding.** Secondary analyses in ongoing cohorts exploring cancer-related genetic, social, behavioral, metabolic and pharmacological factors.
3. **Generation of pilot data that will support new funding.** Generation of preliminary data on novel associations between metabolism and cancer-related outcomes

**ELIGIBILITY**

This pilot grant targets faculty at the Cancer Center and LEAD Center. Eligible faculty include tenure, clinical, research, and instructor tracks. Students, Fellows, and Research Associate level faculty are not eligible.

**FUNDING PROCESS**

Applications are reviewed for scientific merit by selected reviewers with expertise for a given application. The anticipated start date for the award will be Jan 1, 2024. In addition to documentation of regulatory approval, award recipients must meet with the leadership of the respective mechanism prior to receiving the pilot funds. Failing to provide regulatory approval within 3 weeks of notification of will result in delay receipt of grant funds.

**PUBLICATIONS**

All publications, abstracts, or similar dissemination efforts resulting from an award must acknowledge this support by inclusion of the statement: "Supported by a pilot grant from the University of Colorado Cancer Center’s Cancer Prevention and Control Program (P30CA046934) and by the LEAD Center."

**PROGRESS REPORTS**

Two interim progress reports pertaining to specific deliverables will be due at 6 and 12 months. Specific deadlines will be outlined in the award notice. Applicants will use the template provided to report progress on deliverables and milestones; continued project funding will be contingent on timely submission of the progress report and demonstration of sufficient progress. Instructions will be provided on how to submit this report. Please contact Dr. Perng or Dr. Cook with questions.

A final report summarizing the results of the studies, detailing your timeline for pursuing national-level funding, and listing any publications resulting from the work will be due two months following the end date of the award. Awardees will be provided a weblink for submission of their final report 60 days in advance of the due date.

If an extension is needed, you will need to submit an extension request detailing the work that has been completed, the work that remains to be done, and outlining a budget for the remaining funds. Extension requests should be submitted by June 1st, 2024. Submitting an extension request does not automatically waive the requirement for a final report. Only if the extension request is granted is the final report due date moved.

Ongoing updates on project impact in achieving national funding, additional publications, and other outcomes (i.e., patents, or other intellectual property) are required for up to five years following completion of the project. A request for these updates will be made in May/June each year following completion of your project.
**EVALUATION CRITERIA**

Applications will be evaluated using the NIH scoring system (1-9) and parameters (below), supplemented by consideration of the likelihood of leading to external funding and the impact on questions of health equity.

**Significance**
- Does the project address an important problem or a critical barrier to progress in understanding the relationship between cancer and metabolism?
- How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions for cancer and/or metabolic disease?
- Note: cancer-related outcomes do not need to be cancer itself but can be biomarkers of cancer development/risk.

**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?
- Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?

**Approach**
- Are the overall strategy, methodology, and analyses (including power and sample size) justified and appropriate to accomplish the specific aims of the project?
- Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- If the project is in the early stages of development, will the strategy establish feasibility?

**Investigators and community stakeholders (if applicable)**
- Are the PD(s)/PI(s), collaborators, other researchers, and community partners/stakeholders (if appropriate) well suited for the project?
- If the project is collaborative, do the investigators have complementary and integrated expertise?
- Is one PI from the Cancer Center and one from the LEAD Center?
- Is there a brief mentorship plan for the ESI Co-PI?

**Environment**
- Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?
- Is the application consistent with priorities of the Cancer Center and LEAD Center?
- If applicable, does the application offer convincing support regarding community engagement?
- If applicable, does the application incorporate evidence of community engagement?

**Overall impact**
- Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the above review criteria and additional review criteria (as applicable for the project proposed).

**Probability of leading to external funding**
- Does the application make a compelling argument for a trajectory leading to external funding?
- How will funding this application ‘push the research over the top’ for funding - e.g., how does the proposal address a key gap in prior work led by the PIs?
- Does the application provide examples of relevant potential mechanisms for external support?

**Please direct questions to:**
Wei Perng (Wei.Perng@CUAnschutz.edu) or Linda Cook (Linda.Cook@CUAnschutz.edu)
Please note the major tasks or activities involved in the project in the table below. Also specify one or two deliverables or milestones every four months. In addition to the project milestones, please identify a specific sponsor and national-level grant mechanism that you intend to pursue to sustain the research or to advance it to the next level of research/dissemination. (Please adapt as needed)

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