FRED & PAMELA
BUFFETT CANCER CENTER

2023 REQUEST FOR APPLICATIONS
BCC Pilot Projects Program

PROGRAM OVERVIEW

The Buffett Cancer Center (BCC) is accepting applications seeking support for innovative, significant pilot projects in cancer research. The purpose of the BCC Pilot Projects Program is to sponsor high-quality, novel, cancer-focused research to foster the development of promising early-stage projects and encourage their transition to securing external funding.

ELIGIBILITY

- All tenure-leading University of Nebraska faculty members with an academic appointment at or above the level of Assistant Professor are eligible to apply for pilot project funding.
- All project principal investigators must be members of the Buffett Cancer Center. If you are not currently a member of the Cancer Center, please contact Matt Winfrey (winfreym@unmc.edu) to request membership.
- Applicants from populations that are underrepresented in the U.S. biomedical, clinical, behavioral, and social sciences research enterprise are strongly encouraged to submit proposals. Refer to the Notice of NIH's Interest in Diversity [NOT-OD-20-031] for definitions and information about underrepresented populations.

FUNDS AVAILABLE

One-year pilot project awards of up to $50,000 will be made (for single-PI proposals). **To encourage multi-PI and research program- type proposals, developmental awards of up to $75,000 for projects involving two principal investigators and up to $100,000 for SPORE/P01/U01-type projects involving three PIs are also being offered.**

FUNDING TARGET AREAS

This is an omnibus request for applications for projects in five target areas. The objective of this RFA is to help initiate pilot studies that have the potential to develop into nationally funded, high-impact, translational cancer research projects. Priority will be given to projects with the highest scientific merit and those that advance the goals of established or developing research programs or that align with specialized areas of research emphasis within the Cancer Center. The BCC and its collaborating partners have identified research priorities that will enhance the quality of translational cancer research at the University of Nebraska, thereby improving competitiveness for NCI and NIH funding and facilitating comprehensive NCI designation for the BCC. Research programs and areas of research interest targeted for funding include:

#1 – Cancer Biology Program

#2 – Targets, Modulators and Delivery Program

#3 – Gastrointestinal Cancer Program

#4 – Pediatric Cancer, in conjunction with the UNMC/CHMC CHRI Pediatric Cancer Research Group

#5 – Clinical and/or Translational Cancer Research, in collaboration with the Great Plains IDeA-CTR

Applications can be submitted for consideration under more than one target area, if applicable. Areas of strategic focus within these targets are described below:

Focus Areas:

#1 – Cancer Biology Program (CBP):

- Focus on understanding mechanisms that underlie cancer initiation and progression with the potential to lead to new biomarkers and interventional strategies to positively impact cancer diagnosis, prevention, and therapeutic strategies across cancers relevant to the Buffett Cancer Center catchment area.
- Important criteria for all applications will be the likelihood of success for future funding (especially from the NCI and other cancer-focused funding agencies), innovation, high impact (high-impact publications and translation), and qualifications of the PI and Co-PIs/Co-Is.
- Grants that span across the three working themes of the CBP (1. Mechanisms of Genome Stability/Instability, 2. Intra- and Inter-Cellular Signaling Mechanisms that drive tumorigenesis and metastasis, and 3. Investigations of Metabolic Pathways and of Cancer-Host Communication that induce systemic dysfunctions) and those with strong translational potential are particularly encouraged.

#2 – Targets, Modulators and Delivery Program (TMDP):

- Projects to identify and/or validate new cancer targets.
- Projects to develop and use new preclinical models for target evaluation.
- Projects to develop and test novel methods for delivery of small molecules as potential therapeutics.
- Projects to discover and develop small-molecule inhibitors that perturb target function.
- Collaborative projects with other programs.

#3 – Gastrointestinal Cancer Program (GICP):

- Emphasis on research related to colon and pancreas cancers.
- Basic mechanisms of colon and pancreas cancer development and progression; delineation of the metastatic program of colon/pancreas cancer cells.
- Novel biomarkers for treatment decision-making in stage II/III disease colorectal cancer.
- New therapies for metastatic colon cancer.
- Novel biomarkers for detection of disease.
- New projects on colon cancer are especially encouraged.
- Projects with potential for clinical trials, especially trials directed at minority populations in the catchment area that are most impacted by these cancers (e.g., African Americans, Hispanics).
- Research in the epidemiology, outcomes, disparities, and economies of colon/pancreas cancer.

#4 – Pediatric Cancer, in conjunction with the UNMC/Children's Hospital & Medical Center Child Health Research Institute Pediatric Cancer Research Group:

The UNMC/CHMC CHRI Pediatric Cancer Research Group (PCRG) supports research with a focus on pediatric cancer and will be co-funding pilot projects in pediatric cancer research. The PCRG is particularly interested in identifying new cellular and molecular targets in childhood cancers with the potential for therapeutic interventions.

#5 – Clinical and/or Translational Cancer Research, in collaboration with the Great Plains IDeA-CTR:

The Great Plains IDeA-CTR supports research impacting the communities it serves. The goal of the GP IDeA-CTR Pilot Program is to provide support to the most promising and novel clinical and/or translational research (CTR) projects, and help investigators obtain preliminary data necessary for successful investigator-initiated extramural grants.

- Pre-Clinical Research: Pre-clinical research connects the basic science of disease with human medicine. During this stage, scientists develop model interventions to further understand the basis of a disease or disorder and find ways to treat it. Testing is carried out using cell or animal models of disease; samples of human or animal tissues; or computer-assisted simulations of drug, device or diagnostic interactions within living systems.
- Clinical Research: Clinical research includes studies to better understand a disease in humans and relate this knowledge to findings in cell or animal models; testing and refinement of new technologies in people; testing of interventions for safety and effectiveness in those with or without disease; behavioral and observational studies; and outcomes and health services research.
- Clinical Implementation: The clinical implementation stage of translation involves the adoption of interventions that have been demonstrated to be useful in a research environment into routine clinical care for the general population. This stage also includes implementation research to evaluate the results of clinical trials and to identify new clinical questions and gaps in care.
- Public Health: In this stage of translation, researchers study health outcomes at the population level to determine the effects of diseases and efforts to prevent, diagnose and treat them. Findings help guide scientists working to assess the effects of current interventions and to develop new ones.

Thematic Areas: Several cross-cutting themes listed below are of importance to the growth of the cancer center and will also be taken into consideration. Applicants are encouraged to incorporate them to the extent feasible into individual projects. While these themes are of importance, their incorporation should not detract from scientific rigor, which will remain an important review criterion.

- Community Outreach and Engagement (COE): This theme relates to two broad factors: i. serving the needs of people in our catchment area (i.e., the state of Nebraska), with a particular emphasis on the underserved; ii. a bidirectional process. One direction relates to being informed by the community about their perceived needs and, from this, addressing those needs, for example, through a research program. The other direction is primarily driven by "us" to meet a community need.
    - A few clarifying examples:

      i. Underserved: Specific racial/ethnic populations (Hispanic, African American, Native American Indian); certain cohorts (rural, with poor access to health care).

      ii. Community informing research: Our community leaders informed us they have no way to have colonoscopies performed to screen underserved people. In response, we arranged for such, and in parallel, a research project is proposed to perform organoids on resultant tissue and further analyze it, in order to increase our understanding of the biology of cancer in an underserved population, which may or may not be different.

      iii. Research driving changes in the community: Knowing that pancreatic cancer runs a worse clinical course in African Americans, research is proposed to conduct a proteomic analysis to identify factors responsible, with the long-term goal of using them for therapy and/or prognostication.

- Cancer Research Training and Education (CRTE): NIH-designated cancer centers are expected to facilitate cancer research by supporting efforts to foster education and career development for all levels of trainees and faculty.
- Diversity, Equity and Inclusion (DEI). A stipulated NIH goal is to expand DEI in our research work, inclusive of the workforce and in those whom we study. Diversity relates to historically underrepresented groups based on such factors as race/ethnicity, culture, religion, gender, sexual orientation, and/or physical abilities.

APPLICATION GUIDELINES AND RESTRICTIONS

- Investigators are limited to a total of two applications, with no more than one application as PI. (One PI and one MPI, or two MPI applications, maximum.)
- Budget requests should be split equitably between MPIs.
- Kenneth Cowan, Director of the Buffett Cancer Center, cannot serve as a co-investigator on any project. The Cancer Center Deputy Director, Associate Directors, and Program Leaders may serve as PI/MPI or as co-investigator on a project.
- All budget requests for travel (allowed only for recruitment and data collection), equipment, and computer purchases must be clearly and strongly justified in the original justification.
- Budget requests for faculty salaries are not allowed.
- **Regulatory Approvals:**
  - For projects involving human subjects, vertebrate animals, and/or select agents research, prior IRB, IACUC, and/or IBC approval is not required at the time of application submission. However, it is expected that the appropriate protocols will be submitted so approval is imminent at the anticipated project start date. All applicable institutional approvals must be in place before awarded funds can be released. *IRB protocols must be submitted for review within 30 days of notice of award and final IRB approval provided to Cancer Center administration within 60 days of NOA.*
  - For projects involving cancer studies being conducted at UNMC, the relevant protocols must be submitted simultaneously to the IRB and to the BCC Scientific Review Committee (SRC). Contact the BCC Protocol Review and Monitoring System (PRMS) office at 402-559-4232 with questions regarding this process.

APPLICATION FORMAT AND SUBMISSION

The BCC Pilot Projects Program 2023 Application must be used. All applications will be submitted through **NuRamp**.

Required Application Components:

1. **Detailed Budget** with **Budget Justification**
2. **NIH biosketch** for each investigator (5-page limit each)
3. **Other Research Support** information for each PI/MPI. (Other Support for Co-Investigators or Collaborators is not required.) *Note: Other Support demonstrates active and pending support; the purpose of this document is to allow for assessment of an investigator's overall research commitment and to identify any overlap with existing projects.*
4. **Underrepresented Populations Information form**
5. **Description of Proposed Research:**
   - **Scientific Abstract** summarizing the research question, the background of the project, the specific aims, the proposed approach, and the expected outcomes of the project (400-word maximum)
   - **Lay Abstract** that defines the goals and expected outcomes of the project in non-technical terms (250-word maximum)
   - **Research Plan** with the following sections:
     A. Specific Aims (1-page maximum)
     B. Background, Significance and Innovation
     C. Preliminary Studies if any
     D. Approach
     E. Statement of Cancer Relevance (6-page maximum for sections **B-E**)
     F. References Cited
     G. Regulatory compliance information, including **Protection of Human Subjects**, **Vertebrate Animals**, and **Select Agent Research**, as applicable
     - Inclusion of preliminary data is encouraged but not required, and appendices will not be accepted.

General Formatting Requirements: Minimum 0.5-inch margins and Arial 11-point font are required. (Smaller type size may be used for figures and legends.)

Submission Instructions and Deadline:
All applications must be prepared on the NuRamp online application forms by **11:59 pm CT on Tuesday, October 10th, 2023**. The application will be located under " Open Internal Competitions" named Fred & Pamela Buffett Cancer Center Pilot Projects Program 2023. An email will be sent to confirm receipt of the application. Applications will be reviewed in November, and funding notifications are anticipated by December . See "Application Review Process" section below for additional information regarding review procedures.

APPLICATION REVIEW PROCESS

To expedite and to ensure transparency of the review process, a virtual study section will be assembled to review all submitted pilot project applications. This study section will include all application PIs/MPIs, as well as Cancer Center senior leadership and other senior faculty with appropriate expertise. Study section participants will be required to excuse themselves from the review of applications for which they have any identified conflict of interest (e.g., serve as key personnel), but will take part in the discussion and voting process for all other proposals. Depending upon the number of applications received, the study section may take place over a single day or be split into two or more sessions. *The identified study section dates are listed on the pilot project application face page, and PIs/MPIs must indicate their availability to participate in the review when submitting their proposal*. Additional information about the review session will be provided to applicants after the proposal deadline. All applicant PIs/MPIs are expected to participate if able to help facilitate the timely and fair review of proposals. ***Participation in this study section/review panel is very strongly encouraged, although not expressly required.***

- Non-compliant applications will not be reviewed.
- **Violation of confidentiality will result in loss of grant eligibility.**

APPLICATION REVIEW CRITERIA

- Quality of the proposal with respect to significance, innovation, and approach of the research proposed.
- Feasibility of the proposed project with respect to the scope of work and planned milestones / timeline.
- Potential impact on cancer diagnosis, therapy, or outcomes.
- Alignment of the proposed research with the programs and goals of the Cancer Center, as well as with the aims of the relevant funding target area.
- Potential for future funding from national agencies and for impactful peer-reviewed publications.
- Potential to lead to diagnostic or therapeutic clinical trials.

FUNDING AND REPORTING REQUIREMENTS

- Pilot project award recipients are responsible for working with their departmental grants administrator to monitor and manage award funds. It is expected that award funds will be spent within the one-year funding period.
- All pilot project awardees must submit a written progress report at the end of the funding period and be prepared to respond to additional requests for quarterly and semiannual updates from Cancer Center administration and/or its collaborating organizations.
- Awardees are required to provide information to Cancer Center administration regarding any publications and additional funding that result from their pilot project award. Any publications and presentations resulting from a Buffett Cancer Center pilot project award should acknowledge the BCC Cancer Center Support Grant (**CA036727**).
- Awardees are expected to present their research in seminar format as well as to community groups as part of Buffett Cancer Center education and outreach activities, as requested by Cancer Center administration.

ADDITIONAL INFORMATION

For scientific or programmatic questions regarding this funding opportunity, please contact Tony Hollingsworth at mahollin@unmc.edu; for technical or administrative questions, contact Rachel McAllister at ramcallister@unmc.edu.

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY

FROM	THROUGH
1 Feb 2024	31 Jan 2025

List PERSONNEL (Applicant organization only)
Use Cal, Acad, or Summer to Enter Months Devoted to Project
Enter Dollar Amounts Requested (omit cents) for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	PD/PI							
SUBTOTALS →								

CONSULTANT COSTS	
EQUIPMENT *(Itemize)*	
SUPPLIES *(Itemize by category)*	
TRAVEL	
INPATIENT CARE COSTS	
OUTPATIENT CARE COSTS	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*	
OTHER EXPENSES *(Itemize by category)*	

SUBCONTRACT COSTS (if applicable)	DIRECT COSTS	
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		**$**

BUDGET JUSTIFICATION

Personnel:

List all personnel, including names, effort, and roles on the project.

For each person named on the project, it is recommended that the following information be included for clarity:

1. Role, position, department/institution, and suitability to project: Enter relevant work or accomplishment here, which demonstrates suitability to project).
2. Specific role in project (e.g. directing the project, contributing a specific expertise, showing how this is the best person to lead the project.)
3. Commitment of effort to project: S/He is committed to the project for x calendar months.

Example: **John Smith, Ph.D., PI, (1.5 calendar months),** will serve as Principal Investigator and Project Director on this project. Associate Professor in the Department of X at the University of Nebraska Medical Center, he has researched XYZ extensively, and has over X years of highly regarded work in the field. He will have overall responsibility for all aspects of the project and will be responsible for organizing and chairing meetings of the advisory committee. In addition, he will be serving as the lead investigator of the XYZ investigation.

Supplies:

Other Expenses:

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY

A. Personal Statement

B. Positions, Scientific Appointments, and Honors

C. Contributions to Science

OTHER RESEARCH SUPPORT

PI Name

Active

Project Number (Project Contact PI Name) Project Dates Applicant's Effort (Calendar months) Sponsor Name Project Annual Direct Costs
Project Title
Applicant's Role on Project:
The major goals of this project are ____.

Pending

Project Number (Project Contact PI Name) Project Dates Applicant's Effort (Calendar months) Sponsor Name Project Annual Direct Costs
Project Title
Applicant's Role on Project:
The major goals of this project are ____.

Overlap

Summarize any potential overlap with all active or pending projects and this application in terms of the science, budget, and an individual's committed effort.

UNDERREPRESENTED POPULATIONS INFORMATION

Underrepresented Populations in the U.S. Biomedical, Clinical, Behavioral, and Social Sciences Research Enterprise

Despite advancements in scientific research, some populations have not had access to cutting-edge research and training opportunities and do not participate fully in the U.S. sciences research workforce. These underrepresented populations are identified using an evidence-based approach that considers reports from the National Science Foundation, national data sets, and data from the U.S. Department of Health and Human Services. The National Institutes of Health encourages institutions to diversify their student and faculty populations to enhance the participation of individuals from groups that are underrepresented in the biomedical, clinical, behavioral, and social sciences. Innovation and scientific discovery are enhanced by including individuals from diverse groups, including those that are underrepresented in the U.S. sciences research enterprise. Underrepresented groups include individuals from certain racial / ethnic groups, individuals with disabilities, individuals from disadvantaged backgrounds, and women.

The National Cancer Institute also requires NCI-designated cancer centers to develop a Plan to Enhance Diversity. NIH and NCI are committed to ensuring that all Americans share equally in the medical advances that result from cancer research and that current disparities in the burden of cancer are reduced or eliminated. Diversity creates stronger cancer science and is a critical step in reducing the cancer burden for a diverse America.

Definitions and more information about underrepresented populations are available in the Notice of NIH's Interest in Diversity (NOT-OD-20-031) and on the NIH Diversity in Extramural Programs website, and more information about Plans to Enhance Diversity in NCI-designated cancer centers is available in the Cancer Center Support Grant program announcement.

1. Is the Principal Investigator a member of an underrepresented population or populations per NOT-OD-20-031?

☐ **Yes**
☐ **No**
☐ **Prefer not to answer**

2. If "Yes" to Question 1, indicate which underrepresented population(s) by checking the appropriate box(es) below:

☐ **A. Individuals from racial and ethnic groups that have been shown by the National Science Foundation to be underrepresented in health-related sciences on a national basis** (see data at http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27 and the report Women, Minorities, and Persons with Disabilities in Science and Engineering). The following racial and ethnic groups have been shown to be underrepresented in biomedical research: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders. In addition, it is recognized that underrepresentation can vary from setting to setting; individuals from racial or ethnic groups that can be demonstrated convincingly to be underrepresented by the grantee institution should be encouraged to participate in NIH programs to enhance diversity. For more information on racial and ethnic categories and definitions, see the OMB Revisions to the Standards for Classification of Federal Data on Race and Ethnicity (https://www.govinfo.gov/content/pkg/FR-1997-10-30/html/97-28653.htm).

☐ **B. Individuals with disabilities**, defined as those with a physical or mental impairment that substantially limits one or more major life activities, as described in the Americans with Disabilities Act of 1990, as amended. See NSF data at, https://www.nsf.gov/statistics/2017/nsf17310/static/data/tab7-5.pdf.

☐ **C. Individuals from disadvantaged backgrounds**, defined as those who meet *two or more* of the following criteria:

1. Were or currently are homeless, as defined by the McKinney-Vento Homeless Assistance Act (Definition: https://nche.ed.gov/mckinney-vento/);
2. Were or currently are in the foster care system, as defined by the Administration for Children and Families (Definition: https://www.acf.hhs.gov/cb/focus-areas/foster-care);
3. Were eligible for the Federal Free and Reduced Lunch Program for two or more years (Definition: https://www.fns.usda.gov/school-meals/income-eligibility-guidelines);
4. Have/had no parents or legal guardians who completed a bachelor's degree (see https://nces.ed.gov/pubs2018/2018009.pdf);
5. Were or currently are eligible for Federal Pell grants (Definition: https://www2.ed.gov/programs/fpg/eligibility.html);
6. Received support from the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) as a parent or child (Definition: https://www.fns.usda.gov/wic/wic-eligibility-requirements);
7. Grew up in one of the following areas*:
a) a U.S. rural area, as designated by the Health Resources and Services Administration (HRSA) Rural Health Grants Eligibility Analyzer (https://data.hrsa.gov/tools/rural-health), *or*
b) a Centers for Medicare and Medicaid Services-designated Low-Income and Health Professional Shortage Areas (qualifying zip codes are included in the file available at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html).

**Only one of the two possibilities in #7 can be used as a criterion for the disadvantaged background definition.*

Students from low socioeconomic (SES) status backgrounds have been shown to obtain bachelor's and advanced degrees at significantly lower rates than students from middle and high SES groups (see https://nces.ed.gov/programs/coe/indicator_tva.asp), and are subsequently less likely to be represented in biomedical research. For background, see Department of Education data at, https://nces.ed.gov/; https://nces.ed.gov/programs/coe/indicator_tva.asp; https://www2.ed.gov/rschstat/research/pubs/advancing-diversity-inclusion.pdf.

☐ **D. Women in the biomedical workforce.** Literature shows that women from the above backgrounds (categories **A**, **B**, and **C**) face particular challenges at the graduate level and beyond in scientific fields. (See, e.g., From the NIH: A Systems Approach to Increasing the Diversity of Biomedical Research Workforce https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5008902/).

Women have been shown to be underrepresented in doctorate-granting research institutions at senior faculty levels in most biomedical-relevant disciplines, and may also be underrepresented at other faculty levels in some scientific disciplines (See data from the National Science Foundation National Center for Science and Engineering Statistics: Women, Minorities, and Persons with Disabilities in Science and Engineering, special report available at https://www.nsf.gov/statistics/2017/nsf17310/, especially Table 9-23, describing science, engineering, and health doctorate holders employed in universities and 4-year colleges, by broad occupation, sex, years since doctorate, and faculty rank).

Upon review of NSF data, and scientific discipline or field related data, NIH encourages institutions to consider women for faculty-level, diversity-targeted programs to address faculty recruitment, appointment, retention, or advancement.

DESCRIPTION OF PROPOSED RESEARCH

Scientific Abstract (400-word maximum)

Lay Abstract (250-word maximum)

Research Plan:

A. Specific Aims (1-page maximum)

B. Background, Significance and Innovation

C. Preliminary Studies, if applicable

D. Approach

E. Statement of Cancer Relevance (6-page maximum for sections B-E)

F. References Cited

G. Regulatory compliance information, including the following sections as applicable:

- **Protection of Human Subjects** (including **1.** *Risks to Subjects* [with **a.** *Human Subjects Involvement, Characteristics, and Design* and **b.** *Study Procedures, Materials, and Potential Risks*], **2.** *Adequacy of Protection Against Risks* [with **a.** *Informed Consent and Assent*, **b.** *Protections Against Risk*, and **c.** *Vulnerable Subjects, if relevant*], **3.** *Potential Benefits of Proposed Research to Subjects and Others*, and **4.** *Importance of Knowledge to Be Gained*, as applicable);
- **Vertebrate Animals** (including **1.** *Description of Procedures*, **2.** *Justifications*, and **3.** *Minimization of Pain and Distress*); and
- **Select Agent Research** (including **1.** *Identification of Agent(s)*, **2.** *Entity Registration Status*, and **3.** *Description of Facilities*).