



PROGRAM OVERVIEW

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

ELIGIBILITY

- All University of Nebraska faculty members with an academic appointment at or above the level of Instructor are eligible to apply for a pilot project award. (Awards to postdoctoral fellows or graduate students are not allowed.)
- All project principal investigators must be members of the Fred & Pamela Buffett Cancer Center. If you are not currently a member of the Cancer Center, please contact Matt Winfrey (winfreym@unmc.edu) to request membership.
- Projects must focus on some aspect of cancer-related research.

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 seven 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 Buffett Cancer Center and its collaborating organizations have identified research priorities that will enhance the quality of translational research in the Cancer Center and at UNMC, thereby improving competitiveness for NCI and NIH funding and facilitating designation as a comprehensive cancer center. Those 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 – Cancer Prevention and Control

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

#6 – Multiple Myeloma Program

#7 – 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 NCI and other cancer-focused funding), innovation, high impact (likelihood of 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 Cancer to Host Communication to Induce Systemic Dysfunction) 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 – Cancer Prevention and Control:

- Focus on population-based research in cancer etiology, prevention, and control.
- While strength of the proposal, based on NIH review guidelines, will be a driving factor in selection, there are particular attributes that we are seeking to support that will be taken into consideration in determining priority. They include:
 - i. An identified path for pursuing external peer-reviewed funding, and the feasibility of success in achieving such.
 - ii. An identified path for peer-reviewed publication, and the feasibility of success in achieving such.
 - iii. Engagement across disciplines. The following are examples and should not be taken as exclusive: across colleges (e.g., nursing, public health, medicine, pharmacy), across disciplines (e.g., basic, clinical, behavioral).
 - iv. A focus on populations unique to our catchment area of Nebraska, such as rural and underserved minority.
- Proposals that examine genetic, environmental, dietary, sociocultural, behavioral, access to care, and/or other risk factors, factors that are modifiable or not, that are focused on prevention or control, that are interventional or not, are welcome.
- Grants that focus on Nebraska's most compelling and tractable cancer-related problems, and its unique attributes as a state where few people are dispersed over a large area, with distinct rural and urban populations and economies, will be welcome. Such attributes (non-exclusive) include: prevalent and modifiable factors applicable to prevention and/or control, prevalent and preventable cancers, common and severe symptoms, cancers of unusual incidence or poor outcomes, including lower quality of life, unique underserved populations in urban and rural areas.

While not required, researchers are strongly encouraged to partner with communities and/or healthcare organizations in the FPBCC catchment area to conceptualize, develop, and implement the proposed studies.

#5 – 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.

#6 – Multiple Myeloma Program:

- Emphasis on basic, translational, or clinical research related to multiple myeloma and other plasma cell dyscrasias.
- New therapies for multiple myeloma.
- Projects with potential for clinical trials.

#7 – 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.

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 Co-PI, or two Co-PI applications, maximum.)
- 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/Co-PI 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.
- 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 FPBCC Scientific Review Committee (SRC). Contact the FPBCC Protocol Review and Monitoring System (PRMS) office at 402-559-4232 with questions regarding this process.

APPLICATION FORMAT AND SUBMISSION

The appended FPBCC Pilot Projects Program 2021 Application must be used; a version of this application with editable forms is also available.

Required Application Components:

1. **Application Face Page**
2. **Research Project Information form**
3. **Detailed Budget with Budget Justification**
4. **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. **Significance**
 - C. **Innovation**
 - D. **Approach**
 - E. **Preliminary Studies**, if any
 - F. **Statement of Cancer Relevance** (6-page maximum for sections B-F)
 - G. **References Cited**

H. 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.

5. **NIH biosketch** for each investigator (5-page limit each)

6. **Other Research Support** information for each investigator. *Note: Other Support demonstrates active and pending support; the purpose of this document is to allow the reviewer to examine an investigator's overall research commitment and to identify any overlap with existing projects.*

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 forms provided and emailed as a single, complete PDF to buffettcancercenter@unmc.edu, by **11:59 pm CT on Tuesday, November 9, 2021**. The email subject line should list the last name(s) of the principal investigator(s) and the words "Pilot Project Application", followed by the number(s) of the relevant funding target area(s) for the proposal (e.g., "[Hollingsworth Pilot Project Application, #1](#)"). A reply email will be sent to confirm receipt of the application. Applications will be reviewed in December, and funding notifications are anticipated by January. 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 pilot project application PIs, 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 PI or Co-I), but will be encouraged to take part in the discussion and voting process for all other applications. 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 have been listed on the attached pilot project application face page. Additional information about the review session will be provided to all applicants after the proposal deadline. ***Participation in this study section/review panel is very strongly encouraged, although not expressly required.***

APPLICATION REVIEW CRITERIA

- Quality of the proposal with respect to significance, innovation, and approach of the research proposed.
- 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.
- Potential to lead to diagnostic or therapeutic clinical trials.

FUNDING REQUIREMENTS

- Pilot project award recipients are responsible for working with their departmental grants administrator to monitor and manage award funds.
- All pilot project awardees must submit a written progress report at or near the end of the funding period.
- 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.
- Awardees are required to provide information 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 FPBCC Cancer Center Support Grant (P30 CA036727).

ADDITIONAL INFORMATION

For questions regarding this funding opportunity, please contact Tony Hollingsworth at mahollin@unmc.edu or 402.559.8343, or Kelly Jordan at kjordan@unmc.edu or 402.559.4660.

RESEARCH PROJECT INFORMATION

PROJECT TITLE: (200-character maximum)

DOES THE PROJECT INVOLVE HUMAN SUBJECTS? Yes No

If "Yes" to Human Subjects, is the project exempt from federal regulations? Yes No

If "Yes" to exempt, check appropriate exemption number below and provide justification in the space below (attach additional pages if necessary):

Exemptions: 1 2 3 4 5 6 7 8

If "No" to Human Subjects, does the proposed research involve human specimens and/or data?

Yes No

If "Yes" to human specimens and/or data, provide an explanation of why the project does not involve human subjects research in the space below (attach additional pages if necessary):

DOES THE PROJECT INVOLVE VERTEBRATE ANIMALS? Yes No

If "Yes" to Vertebrate Animals, are the animals euthanized? Yes No

If "Yes" to euthanasia, is the method consistent with AVMA guidelines? Yes No

If "No" to AVMA guidelines, describe the method and provide scientific justification in the space provided below (attach additional pages if necessary):

DOES THE PROJECT INVOLVE SELECT AGENT(S)? Yes No

(See Federal Select Agent Program list: <https://www.selectagents.gov/SelectAgentsandToxinsList.html>)

If "Yes" to Select Agent(s), is/are the agent(s) excluded from federal regulations? Yes No

(See FSAP exclusions: <https://www.selectagents.gov/SelectAgentsandToxinsExclusions.html>)

**DETAILED BUDGET FOR INITIAL BUDGET PERIOD
DIRECT COSTS ONLY**

FROM
1 Feb 2022

THROUGH
31 Jan 2023

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 →

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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:

DESCRIPTION OF PROPOSED RESEARCH

Scientific Abstract (400-word maximum)

Lay Abstract (250-word maximum)

Research Plan:

A. Specific Aims (1-page maximum)

B. Significance

C. Innovation

D. Approach

E. Preliminary Studies (if applicable)

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

G. References Cited

H. 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**).

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 <i>(if applicable)</i>	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)

Sponsor Name

Project Title

Applicant's Role on Project:

The major goals of this project are ____.

Project Dates

Applicant's Effort (Calendar months)

Project Annual Direct Costs

Pending

Project Number (Project Contact PI Name)

Sponsor Name

Project Title

Applicant's Role on Project:

The major goals of this project are ____.

Project Dates

Applicant's Effort (Calendar months)

Project Annual Direct Costs

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