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 University of Nebraska faculty members with an academic appointment at or above the level of Instructor are eligible to apply for pilot project funding. (Awards to postdoctoral fellows or graduate students are not allowed.)
- 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.
- 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 six 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 – Multiple Myeloma Program
#6 – 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 – 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.

#6 – 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 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 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 appended BCC Pilot Projects Program 2022 Application must be used; editable forms are 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. 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.
5. NIH biosketch for each investigator (5-page limit each)
6. **Other Research Support** information for each PI/Co-PI. (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 examination of 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 Wednesday, November 2, 2022. 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., “Smith 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 application PIs/Co-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 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/Co-PIs 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/Co-PIs 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.

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.
- 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 (P30 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.
1. PROJECT SENIOR / KEY PERSONNEL

<table>
<thead>
<tr>
<th>1. PRINCIPAL INVESTIGATOR</th>
<th>2. CO-PRINCIPAL INVESTIGATOR(S) (if applicable)</th>
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<tr>
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<td>1c. DEPARTMENT / DIVISION:</td>
<td>2c. DEPARTMENT(S) / DIVISION(S):</td>
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3. CO-INVESTIGATOR(S) (if applicable)

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<tr>
<td>3b. POSITION TITLE(S) / ACADEMIC RANK(S):</td>
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<td>3c. DEPARTMENT(S) / DIVISION(S):</td>
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4. COSTS REQUESTED FOR PROPOSED BUDGET PERIOD:

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<th>Direct Costs ($)</th>
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5. WILL THE PROJECT INCLUDE SUB-AWARDS OR SUB-CONTRACTS?

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<tr>
<th>YES</th>
<th>NO</th>
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6. DEPARTMENTAL FINANCIAL OFFICIAL TO BE NOTIFIED IF AWARD IS MADE:

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<th>Name:</th>
<th>Tel:</th>
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<tr>
<td>Title:</td>
<td>Email:</td>
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7. APPLICATION REVIEW SESSION / STUDY SECTION DATES; PLEASE CHECK ALL DATES FOR WHICH THE PI(s) WILL BE AVAILABLE TO PARTICIPATE IN THE REVIEW:

<table>
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<tr>
<th>☐ FRIDAY, DECEMBER 9, 2022*</th>
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<tr>
<td>*Main study section date.</td>
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| ☐ THURSDAY, DECEMBER 8, 2022** |
| **Additional study section date if needed, depending on the number of applications received. |

8. PLEASE INDICATE THE RESEARCH TARGET AREA(S) FOR WHICH THE PROPOSAL IS BEING SUBMITTED:

- [ ] Target #1: Cancer Biology Program (CBP)
- [ ] Target #2: Targets, Modulators and Delivery Program (TMDP)
- [ ] Target #3: Gastrointestinal Cancer Program (GICP)
- [ ] Target #4: Pediatric Cancer
- [ ] Target #5: Multiple Myeloma Program
- [ ] Target #6: Clinical and/or Translational Cancer Research
**PILOT PROJECT INFORMATION**

**PROJECT TITLE:** (200-character maximum)

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**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 ☐

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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):

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**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):

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**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)
PILOT PROJECT INFORMATION, CONTINUED

CANCER CENTER SHARED RESOURCES:
If the proposed project will utilize any of the Buffett Cancer Center-supported shared resources/core facilities listed below, check the boxes as applicable:

☐ Advanced Microscopy: UNMC Advanced Microscopy Core Facility
☐ Bioinformatics: UNMC Bioinformatics and Systems Biology Core Facility
☐ Biostatistics: UNMC Center for Collaboration on Research Design and Analysis (CCORDA)
☐ Flow Cytometry: UNMC Flow Cytometry Research Facility
☐ Molecular Biology: UNMC Genomics Core Facility and Eppley Institute Molecular Biology/HTS Core Facility
☐ Pathology: UNMC Tissue Sciences Facility and Tissue Procurement Shared Resource
☐ Preclinical Imaging: UNMC In Vivo Imaging Core Facility, Echocardiography Imaging Facility, and Multiphoton Intravital & Tissue Imaging Core
☐ Structural Biology: UNMC NMR Facility and Eppley Institute Structural Biology Facility

CANCER CENTER COMMUNITY OUTREACH AND ENGAGEMENT:
Buffett Cancer Center (BCC) Community Outreach and Engagement (COE) efforts are focused on reducing the cancer burden, promoting health equity, and eliminating cancer health disparities in Nebraska through collaboration with community, clinical, and public health partners. BCC COE has the following aims:

• Understand, measure, and monitor the cancer incidence, mortality, determinants, community needs, and disparities in Nebraska over time.
• Facilitate and enable the conduct of research directly relevant to the needs in Nebraska and improve access to clinical trials across the state.
• Engage Nebraskans and implement evidence-based actions that can reduce the burden of risk factors and cancers at a population level.
• Promote translation of BCC research with support from strong community partnerships to inform state cancer policies.

To access the 2022 Nebraska Statewide Cancer Needs Assessment Report and the 2021 Nebraska Community Health Needs Assessment Reports, visit: https://www.unmc.edu/cancercenter/outreach/coeo/coeo-reports.html

USE the space below to briefly describe how the project will support the BCC COE aims, if applicable (attach additional pages if necessary):

CANCER CENTER CANCER RESEARCH TRAINING AND EDUCATION:
Buffett Cancer Center (BCC) Cancer Research Training and Education (CRTE) efforts are focused on overseeing training and education relevant to cancer to ensure the development of future cancer researchers in Nebraska, while complementing the ongoing research in the BCC research programs by taking a central role in driving the progress of cancer research forward. BCC CRTE has the following aims:

• Provide cancer-related education and training to middle, high school, and undergraduate students in programs which emphasize the inclusion of students who are disadvantaged.
• Educate students who are in graduate and professional programs in cancer research to prepare them for academic, industry, and clinical leadership positions.
• Offer training to enable fellows, junior faculty, and senior faculty members to reach high educational and research goals focused on cancer.

USE the space below to briefly describe how the project will support the BCC CRTE aims, if applicable (attach additional pages if necessary):

CANCER CENTER DIVERSITY, EQUITY AND INCLUSION:
As an NCI-designated cancer center, the Buffett Cancer Center’s (BCC) Diversity, Equity and Inclusion (DEI) efforts are focused on 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. BCC DEI aims include:

• Enhance participation of women, minorities, and individuals from groups nationally underrepresented in the research workforce and center membership.
• Support career-enhancing research opportunities for junior, early- and mid-career researchers, including those from diverse backgrounds.
• Expand the pipeline of members of diverse backgrounds through training or mentoring opportunities to encourage participation of students, postdoctoral researchers, and co-investigators from diverse backgrounds, including those groups shown to be nationally underrepresented in the research workforce.

USE the space below to briefly describe how the project will support the BCC DEI aims, if applicable (attach additional pages if necessary):
## DETAILED BUDGET FOR INITIAL BUDGET PERIOD
### DIRECT COSTS ONLY

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

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<th>Cal. Mnths</th>
<th>Acad. Mnths</th>
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**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)*

**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. 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:
   - 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.)

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A. Personal Statement

B. Positions, Scientific Appointments, and Honors

C. Contributions to Science
# OTHER RESEARCH SUPPORT

**PI Name**

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<th>Overlap</th>
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<td>Project Number (Project Contact PI Name)</td>
<td>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</td>
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