



2018 REQUEST FOR APPLICATIONS Fred & Pamela Buffett Cancer Center Pilot Projects Program

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 in order 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.)
- The project Principal Investigator(s) 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 (winfrey@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). **In order to encourage multi-PI and research program-type proposals, developmental awards of up to \$75,000 for multi-PI projects involving two Principal Investigators and up to \$100,000 for SPORE/P01/U01-type projects involving three PIs are also being offered.** *Larger multi-PI awards can only be made for proposals submitted for consideration under funding target areas #1-5; see below for further details regarding target areas.*

FUNDING TARGET AREAS

This is an omnibus request for applications for projects in eight target areas. The objective of this RFA is to help initiate pilot research projects 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 quality of translational research in the Cancer Center and at UNMC, thereby improving competitiveness for NCI and NIH funding and designation as a comprehensive cancer center. Those research programs or areas of research interest targeted for funding include:

- #1 – Molecular and Biochemical Etiology of Cancer Program**
- #2 – Cancer Genes and Molecular Regulation Program**
- #3 – Gastrointestinal Cancer Program**
- #4 – Cancer Prevention and Control**
- #5 – Pediatric Cancer, in collaboration with the UNMC Pediatric Cancer Research Center**
- #6 – Multiple Myeloma Program**
- #7 – Clinical and/or Translational Cancer Research, in collaboration with the Great Plains IDeA-CTR**
- #8 – SPORE in Pancreatic Cancer Developmental Research Program**

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 – MBEP (Molecular and Biochemical Etiology of Cancer Program)

- Focus on the discovery and validation of new cancer cell-intrinsic or -extrinsic (including stromal/immune cell) mechanisms of cancer initiation and progression that could lead to identification/validation of new cancer biomarkers or therapeutic targets.
- Important criteria for all applications will be the likelihood of success for future funding (especially NCI funding), innovation, impact, and qualifications of the PI and Co-PIs/Co-Is.
- Grants that span across the three working themes of the MBEP (Genome Integrity, Cell Cycle and Survival, and Extra-Cellular Mediators of Oncogenesis) and those with translational potential are particularly encouraged.

#2 – CGMRP (Cancer Genes and Molecular Regulation Program)

- 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 – GICP (Gastrointestinal Cancer Program)

- 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.

#4 – Cancer Prevention and Control

- Focus on population-based research in cancer etiology, prevention, and control, with priority given to studies that include rural and underserved areas in Nebraska.
- Grants that study modifiable cancer risk factors to improve cancer prevention and progression in rural, underserved, and at-risk populations, including but not limited to environmental factors, behavioral factors, sociocultural issues, and access to care.
- Grants that evaluate new or existing interventions to address cancer disparities in the FPBCC catchment area.
- Grants that address cancer patients' preferences throughout the continuum of cancer care.
- Grants that focus on Nebraska's most compelling and tractable cancer-related problems (e.g., prevalent and modifiable risk factors, prevalent and preventable cancers, common and severe symptoms, cancers of unusual incidence or poor outcomes, including lower quality of life).

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 collaboration with the UNMC Pediatric Cancer Research Center

The UNMC Pediatric Cancer Research Center (PCRC) supports research with a focus on pediatric cancer, and will be co-funding pilot projects in pediatric cancer research. The PCRC 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 and will be co-funding up to two pilot awards for cancer research. 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.

- Clinical research involves human subjects (or material of human origin such as tissues, specimens, or cognitive phenomena) for which an investigator directly interacts with human subjects.
- Translational research involves moving research on treatments, diagnostics and prevention from the laboratory and pre-clinical settings to patient- and population-based settings.

#8 – SPORE in Pancreatic Cancer Developmental Research Program

Funds are available through the Developmental Research Program (DRP) of the SPORE in Pancreatic Cancer for projects that are translational in nature. For the SPORE program, NCI defines translational research as follows: "*Translational research uses knowledge of human biology to develop and test the feasibility of cancer-relevant interventions in humans and/or determines the biological basis for observations made in individuals with cancer or in populations at risk for cancer.*" As noted in the SPORE PAR, "The term "interventions" is used in its broadest sense to include molecular assays, imaging techniques, drugs, biological agents, and/or other methodologies applicable to the prevention, early detection, diagnosis, prognosis, and/or treatment of cancer. SPORE

translational research projects may involve the use of any cellular, molecular, structural, biochemical, and/or genetic experimental approaches.”

The principal goal of the DRP is to fund promising projects that address important translational objectives in prevention, early detection, prognosis, and therapy of pancreatic adenocarcinoma. It is our intent to fund projects that have the potential to develop into full SPORE projects by this award mechanism. (Guidelines for full SPORE projects are described in Appendix A.) While proposed projects need not fulfill all of these criteria at this time, there should be evidence that the project could develop into a full SPORE project within three years. See the full SPORE DRP guidelines included starting on page 5 of this announcement for more information about this funding target area.

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, MD, PhD, Director of the Fred & Pamela Buffett Cancer Center, cannot serve as a co-investigator on any project. Associate Directors and Program Leaders of the Cancer Center may serve as the PI/Co-PI or as a co-investigator on a project.
- Travel is allowed only for recruitment and data collection, and it must be clearly justified in the final detailed budget.
- All requests for equipment must be strongly justified, and all computer purchases must be justified in the final detailed budget.
- Requests for faculty salaries are not allowed.
- Prior approval of IRB and/or IACUC protocols is not necessary; however, it is expected that IRB or IACUC protocols will be submitted so approval is imminent at the anticipated start date. All regulatory approvals as applicable must be in place before awarded funds may be spent.

APPLICATION FORMAT AND SUBMISSION

Required Application Components:

For all applications being submitted for Target Areas #1-7:

1. Application face page including the title of the project and the names, professional titles, and roles of each applicant investigator. **(See attached face page form.)**
2. Abstract summarizing the research question, the background of the project, the specific aims, the proposed approach, and the expected outcomes of the project. **(350-word maximum.)**
3. Lay abstract that defines the goals and expected outcomes of the project in non-technical terms. **(250-word maximum.)**
4. Research Plan **(six-page limit, not including References)** with the following sections:
 - a. Specific Aims;
 - b. Background and Significance;
 - c. Innovation;
 - d. Preliminary Studies;
 - e. Research Design and Methods;
 - f. Statement of Cancer Relevance; and
 - g. References Cited.
 - Inclusion of preliminary data is encouraged, but not required, and appendices will not be accepted.
 - ***Applicants should include a discussion of h) Human Subjects; i) Animal Welfare; and j) Select Agent Research, as applicable.***
5. NIH biosketch for each investigator. **(Five-page limit; see attached biosketch form page.)** *Note: The Section D. Research Support portion of the NIH biosketch documents ongoing and recently completed (within the last three years) support; the purpose of this part of the document is to highlight an investigator's research accomplishments and to allow the reviewer to evaluate the qualifications of the research team.*
6. Other Support information for each investigator. **(See attached Other Support form page example.)** *Note: Other Support documents current 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.*
7. Modular Budget* and Personnel Justification: Complete the Federal Detailed Budget for Initial Budget Period Direct Costs Only form *with personnel and effort information only* **(see attached modified Form Page 4)** and provide a Personnel Justification.

*Only a modular budget is required at the time of submission; if the proposal is selected for funding, Cancer Center administration will work with the Principal Investigator(s) to establish a final detailed budget for the project.

For applications being submitted for Target Area #8 (SPORE Developmental Research Program) ONLY: Complete all application requirements as detailed in the attached SPORE DRP guidelines beginning on page 5 of this announcement.

Formatting Requirements (for applications being submitted for all target areas):

- Font: Arial; Type size: 11-point minimum (smaller type size is permitted for figures and tables; type must be legible); Type color: Black.
- Minimum of 0.5-inch margins on all sides.

Submission Instructions and Deadline:

All applications must be prepared on the forms provided and emailed as a single, complete PDF to kjordan@unmc.edu, by **5:00 PM CT on Monday, October 1, 2018**. The email subject line should list the last name of the Principal Investigator and the words “pilot project application”, followed by the number(s) of the relevant funding target area(s) for the proposal. (Example: “Hollingsworth, Pilot Project Application, #1”). A reply email will be sent to confirm receipt of the application. It is anticipated that applications will be reviewed in November 2018, with grants awarded and funding initiated within two months after the review process is completed. See “Application Review Process” section below for additional information regarding review procedures.

APPLICATION REVIEW PROCESS

In order to expedite and to ensure transparency of the review process, a study section will be assembled to review all submitted pilot project applications. This study section will include all investigators who submitted an application, 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 proposal PI or Co-I), but will be encouraged to take part in the discussion, evaluation, 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. Potential study section dates under consideration have been listed on the attached pilot project application face page; when completing this form, applicants should identify *all* dates for which they can be available. Study section date(s) for which the greatest number of reviewers can participate will be identified after the application deadline. *Participation in this study section/review panel is not required, but is very strongly encouraged.*

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 additional information or 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.

SPORE IN PANCREATIC CANCER

2018 DEVELOPMENTAL RESEARCH PROGRAM

Funds are available through the Developmental Research Program (DRP) of the SPORE in Pancreatic Cancer for projects that are translational in nature. For the SPORE program, NCI defines translational research as follows: "*Translational research uses knowledge of human biology to develop and test the feasibility of cancer-relevant interventions in humans and/or determines the biological basis for observations made in individuals with cancer or in populations at risk for cancer.*" As noted in the SPORE PAR, "The term "interventions" is used in its broadest sense to include molecular assays, imaging techniques, drugs, biological agents, and/or other methodologies applicable to the prevention, early detection, diagnosis, prognosis, and/or treatment of cancer. SPORE translational research projects may involve the use of any cellular, molecular, structural, biochemical, and/or genetic experimental approaches."

The principal goal of the DRP is to fund promising projects that address important translational objectives in prevention, early detection, prognosis, and therapy of pancreatic adenocarcinoma. It is our intent to fund projects that have the potential to develop into full SPORE projects by this award mechanism. (Guidelines for full SPORE projects are described in Appendix A.) While proposed projects need not fulfill all of these criteria at this time, there should be evidence that the project could develop into a full SPORE project within three years.

Key elements that determine priority in the DRP program are innovation, novelty, and potential for success in translational pancreatic cancer research.

To qualify as a *translational project*, ***projects must focus on translational objectives in prevention, early detection, or therapy of pancreatic adenocarcinoma.***

Collaborative, multi-investigator projects are encouraged but not required. Full SPORE projects must include a basic science component and a clinical translational component. Although not required for these Developmental Projects, descriptions of plans and a realistic timeline for incorporating both basic and clinical co-investigators into the project should be included.

All Developmental Funds will be awarded by competition based on submission of an NIH-style pilot project application, and will be scored according to the NIH scoring system.

There will be a two-tier review process for proposals. First, a scientific review of each grant will occur, followed by a review by selected members of the SPORE advisory bodies.

SPORE DRP Criteria for Review of Applications:

1. Membership (member or associate member) of PI and co-PIs in the UNMC Fred & Pamela Buffett Cancer Center.
2. ***Focus on pancreas cancer adenocarcinoma-related research.***
3. Every proposed project must have a clear translational objective. For the SPORE program, translational research is defined as research that uses knowledge of human biology to develop and test the feasibility of cancer-relevant interventions in humans and/or determines the biological basis for observations made in individuals with cancer or in populations at risk for cancer. The term "interventions" is used in its broadest sense to include molecular assays, imaging techniques, drugs, biologicals and/or other methodologies that are relevant to the prevention, early detection, diagnosis, prognosis or treatment of cancer. Translational research in NCI SPORE projects is always founded on and directly connected to some aspect of human biology and may involve the use of any cellular, molecular, structural, biochemical, genetic, or other appropriate experimental approach (<http://trp.cancer.gov>).
4. Quality, novelty, and innovativeness of the research proposed.
5. Potential for future funding and inclusion in the SPORE program (including plans for incorporating basic and clinical co-investigators into the project).

SPORE Developmental Research Program Grant Applications should include the following:

1. Application face page including the title of the project and the names, professional titles, and roles of each applicant investigator. **(See attached face page form.)**
2. Abstract summarizing the research question, the background of the project, the specific aims, the proposed approach, and the expected outcomes of the project. **(350-word maximum.)**
3. Lay abstract that defines the goals and expected outcomes of the project in non-technical terms. **(250-word maximum.)**
4. Research Plan **(six-page limit**, not including References) with the following sections:
 - a. Specific Aims and Statement of Translational Potential;
 - b. Background and Significance;

- c. Innovation;
- d. Preliminary Studies;
- e. Research Design and Methods;
- f. Statement of Cancer Relevance; and
- g. References Cited.

- Inclusion of preliminary data is encouraged, but not required, and appendices will not be accepted.
- ***Applicants should include a discussion of h) Human Subjects; i) Animal Welfare; and j) Select Agent Research, as applicable.***

5. NIH biosketch for each investigator. **(Five-page limit; see attached biosketch form page.)** *Note: The Section D. Research Support portion of the NIH biosketch documents ongoing and recently completed (within the last three years) support; the purpose of this part of the document is to highlight an investigator's research accomplishments and to allow the reviewer to evaluate the qualifications of the research team.*
6. Other Support information for each investigator. **(See attached Other Support form page example.)** *Note: Other Support documents current 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.*
7. Modular Budget* and Personnel Justification: Complete the Federal Detailed Budget for Initial Budget Period Direct Costs Only form with personnel and effort information only **(see attached modified Form Page 4)** and provide a Personnel Justification.

*Only a modular budget is required at the time of submission; if the proposal is selected for funding, Cancer Center administration will work with the Principal Investigator(s) to establish a final detailed budget for the project.

Additional SPORE DRP Guidelines:

1. 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.)
2. Prior approval of IRB and/or IACUC protocols is not necessary; however, it is expected that IRB or IACUC protocols will be submitted so approval is imminent at the anticipated start date.
3. Applications should be NIH-style project application.
 - Proposals should include the following sections: a) Specific Aims; b) Background and Significance; c) Innovation; d) Preliminary Studies/Progress Report (for renewal applications, if applicable); e) Research Design and Methods.
 - ***The Research Design and Methods (e) must include a set of quantifiable milestones for achievement that represent acceptable progress by the end of the first year.***
 - ***Milestones could be one of the following: 1) Preparation, submission, acceptance of manuscripts; 2) Initiation and conduct of clinical trials or deployment of newly developed diagnostic tests; 3) Initiation and conduct of basic laboratory studies that arise from results of clinical trials or important questions that have arisen from clinical observations; 4) submission of an R03, R21, or R01 application to NCI on the subject of the Developmental Project.***
4. **PI Salary Support is not allowed.**
5. The only travel allowed is to collect patient samples, and it must be clearly justified.
6. All requests for equipment must be **strongly** justified, and all computer purchases must be justified in the original budget.
7. Investigators may request renewal funding for a second or third year by submitting a progress report and a new application.

If you have any questions regarding the SPORE DRP, please contact Tony Hollingsworth, 402.559.8343, (mahollin@unmc.edu), or Cindy Plate, 402.559.4192, (cjplate@unmc.edu).

Appendix A - [Major Components of SPORE Projects]

Research Projects

Research projects may be conducted solely through the parent institution, or through collaborative associations that have been developed and/or are planned with other SPOREs and/or with other investigators in the biomedical research community. However, all SPOREs should meet the following criteria:

- Each proposed project must meet the definition of translational research as described below.
- Each proposed research project should be designed to test the relevance and/or potential importance of the research to human cancer within the project period of the grant. Projects containing basic research, e.g., employing animal models or cell lines qualify as translational only if a human application is included in the specific aims.
- SPORE projects should represent a balance and diversity of translational research objectives (e.g., early detection, prevention, diagnosis, treatment). Applications with a specific theme (e.g., gene therapy in prostate cancer) are discouraged.

For the SPORE program, NCI defines translational research as follows:

Translational research uses knowledge of human biology to develop and test the feasibility of cancer-relevant interventions in humans and/or determines the biological basis for observations made in individuals with cancer or in populations at risk for cancer.

As noted in the SPORE PAR, "The term "interventions" is used in its broadest sense to include molecular assays, imaging techniques, drugs, biological agents, and/or other methodologies applicable to the prevention, early detection, diagnosis, prognosis, and/or treatment of cancer. SPORE translational research projects may involve the use of any cellular, molecular, structural, biochemical, and/or genetic experimental approaches."

Specific Aims: State concisely the translational goals of the proposed Research Project and summarize the expected translational outcomes(s), including the impact that the results of the Research Project will exert on the human disease site(s) involved. List succinctly the specific objectives of the Research Project, e.g., to test a stated hypothesis, to generate new hypotheses relevant to translational research, to solve a specific problem that has yet been unsolved in the field, to challenge an existing paradigm or clinical practice, to address any critical barrier(s) to progress in the field of translational cancer research, or to develop new technologies, detection methods, or biomarkers appropriate for testing in human cancer patients or populations at risk for cancer. At least one specific aim must address a human endpoint.

It should be noted that a clinical trial may not be the goal of many SPORE projects. Some projects will reach a human endpoint by using human specimens in the laboratory to expand upon observations made in the clinic, a process known as "reverse translation." However, when biomarker studies are ready for clinical trials, SPOREs are encouraged to collaborate with trans-NCI clinical trial mechanisms to validate the biomarkers clinically.

The following types of human endpoints are acceptable to qualify SPORE projects as translational and programmatically responsive:

- Early phase clinical trials of new investigational drugs and biologics, experimental procedures, medical devices, or combinations thereof, or
- Early phase clinical trials of new combinations or new uses of the FDA-approved agents and devices, or
- Discovery and development of biomarkers, only when measurements are made in human specimens, or directly in human subjects, or
- IND-directed toxicology studies* conducted following a pre-IND meeting with the FDA in which the plan proposed by the investigators is acceptable to the FDA, or
- Population, behavioral, or psychosocial studies, when these studies address mechanistic aspects of the biology of the disease, or
- Laboratory studies that begin with an observation in the clinic and use human specimens to generate new clinical hypotheses.

Please note that examples of translational research are provided, but translational research is not restricted to projects such as these.



FRED & PAMELA
**BUFFETT
CANCER
CENTER**

Fred & Pamela Buffett Cancer Center Pilot Projects Program 2018 Request for Applications

Application Deadline: 5:00 pm CT, Monday, October 1, 2018

1, 2 & 3. PROJECT SENIOR / KEY PERSONNEL

| | | | |
|-------------------------------------|---------|--|--|
| 1. PRINCIPAL INVESTIGATOR | | 2. CO-PRINCIPAL INVESTIGATOR(S) (if applicable) | |
| 1a. NAME: | | 2a. NAME(S): | |
| | | | |
| 1b. POSITION TITLE / ACADEMIC RANK: | | 2b. POSITION TITLE(S) / ACADEMIC RANK(S): | |
| | | | |
| 1c. DEPARTMENT: | | 2c. DEPARTMENT(S): | |
| | | | |
| 1d. MAJOR SUBDIVISION: | | 3. CO-INVESTIGATOR(S) (if applicable) | |
| 1e. MAILING ADDRESS: | | 3a. NAME(S): | |
| | | | |
| 1f. CONTACT INFORMATION: | | 3b. POSITION TITLE(S) / ACADEMIC RANK(S): | |
| | | | |
| TEL: | E-MAIL: | 3c. DEPARTMENT(S): | |
| | | | |

4. TITLE OF PROJECT:

| | | | |
|--|-----------------------------------|--|-----------------------------------|
| 5. COSTS REQUESTED FOR PROPOSED BUDGET PERIOD: (Indirect Costs not allowed) Direct Costs (\$): | | 6. WILL THE PROJECT INCLUDE SUB-AWARDS OR SUB-CONTRACTS? YES <input type="checkbox"/> NO <input type="checkbox"/> | |
| 7. HUMAN SUBJECTS RESEARCH? <input type="checkbox"/> No <input type="checkbox"/> Yes | | 8. VERTEBRATE ANIMALS RESEARCH? <input type="checkbox"/> No <input type="checkbox"/> Yes | |
| 7a. Research Exempt? <input type="checkbox"/> No <input type="checkbox"/> Yes | 7b. If "Yes," Exemption No.: | 8a. If "Yes," IACUC approval date: | 8b. Animal Welfare Assurance No.: |
| | 7c. Human Subjects Assurance No.: | | |
| 9. DEPARTMENTAL FINANCIAL OFFICIAL TO BE NOTIFIED IF AWARD IS MADE: Name: Tel: Title: E-mail: | | 10. PLEASE CHECK ALL DATES FOR WHICH THE PI / CO-PIs WILL BE AVAILABLE TO PARTICIPATE IN THE APPLICATION REVIEW SESSION / STUDY SESSION: <input type="checkbox"/> WEDNESDAY, NOVEMBER 7, 2018 <input type="checkbox"/> MONDAY, NOVEMBER 12, 2018 <input type="checkbox"/> THURSDAY, NOVEMBER 8, 2018 <input type="checkbox"/> TUESDAY, NOVEMBER 13, 2018 <input type="checkbox"/> FRIDAY, NOVEMBER 9, 2018 | |

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

- ☐ Target #1: Molecular and Biochemical Etiology of Cancer Program (MBEP)
- ☐ Target #2: Cancer Genes and Molecular Regulation Program (CGMRP)
- ☐ Target #3: Gastrointestinal Cancer Program (GICP)
- ☐ Target #4: Cancer Prevention and Control
- ☐ Target #5: Pediatric Cancer, in collaboration with the UNMC Pediatric Cancer Research Center
- ☐ Target #6: Multiple Myeloma Program
- ☐ Target #7: Clinical and/or Translational Cancer Research, in collaboration with the Great Plains IDeA-CTR
- ☐ Target #8: SPORE in Pancreatic Cancer Developmental Research Program

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 and Honors
- C. Contributions to Science
- D. Additional Information: Research Support and/or Scholastic Performance

For New and Renewal Applications – DO NOT SUBMIT UNLESS REQUESTED**PHS 398 OTHER SUPPORT**

Provide active and pending support for all senior/key personnel. **Other Support includes all financial resources, whether federal, non-federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.** Training awards, prizes, or gifts do not need to be included.

There is no "form page" for reporting Other Support. Information on Other Support should be provided in the *format* shown below.

For information pertaining to the use of and policy for other support, see NIH Grants Policy Statement, Section 2.5.1: Just-in-Time Procedures. Neither the application under consideration nor the current PHS award for this project should be listed as Other Support.

Effort devoted to projects must be measured using "person months." NIH and other PHS agencies use the concept of "person months" as a metric for determining percent of effort. For more information about calculating person months, see NIH's Frequently Asked Questions on Person Months.

Format**NAME OF INDIVIDUAL****ACTIVE/PENDING**

Project Number (Contact Principal Investigator)

Source

Title of Project (*or Subproject*)

Dates of Approved/Proposed Project

Annual Direct Costs

Person Months

(Cal/Academic/
Summer)

The major goals of this project are...

OVERLAP (*summarized for each individual*)**Instructions for Selected Items**

Project Number: If applicable, include a code or identifier for the project.

Source: Identify the agency, institute, foundation, or other organization that is providing the support. Include institutional, federal, public, and private sources of support.

Major Goals: Provide a brief statement of the overall objectives of the project, subproject, or consortium/contractual arrangement.

Dates of Approved/Proposed Project: Indicate the inclusive dates of the project as approved/proposed. For example, in the case of NIH support, provide the dates of the approved/proposed competitive segment.

Annual Direct Costs: In the case of an active project, provide the current year's direct cost budget. For a pending project, provide the proposed direct cost budget for the initial budget period.

Percent Effort/Person Months: Indicate calendar, academic, and/or summer months associated with each project. For an active project, provide the level of actual effort in person months (even if unsalaried) for the current budget period. Person months should be classified as academic, calendar, and/or summer. For a pending project, indicate the level of effort in person months as proposed for the initial budget period. Use either calendar months OR a combination of academic and summer months. If effort does not change throughout the year, it is OK to use only calendar months. However, you may use both academic and summer months if your institutional business process requires noting each separately even if effort remains constant. If effort varies between academic and summer months, use only academic and summer months, and do not use calendar months. In cases where an individual's appointment is divided into academic and summer segments, indicate the proportion of each devoted to the project.

Overlap: After listing all support, summarize for each individual any potential overlap with the active or pending projects and this application in terms of the science, budget, or an individual's committed effort.

Note for Other Support provided under a consortium/contractual arrangement or that is part of a multi-project award: Indicate the project number, PD/PI, and source for the overall project, and provide all other information for the subproject only.

Special Instructions for Joint University and Department of Veterans Affairs (VA) Appointments

Individuals with joint university and VA appointments may request the university's share of their salary in proportion to the effort devoted to the research project. The individual's salary with the university determines the base for computing that request. Signature by the Institutional Official on the application certifies that: (1) the individual is applying as part of a joint appointment specified by a formal Memorandum of Understanding between the university and the VA; and (2) there is no possibility of dual compensation for the same work, or of an actual or apparent conflict of interest regarding such work. Additional information may be requested by the awarding component(s).

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

FROM
1 Jan. 2019

THROUGH
31 Dec. 2019

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 | | | | | | | |
| | | | | | | | | |
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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)

DIRECT COSTS

TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD

\$

PERSONNEL JUSTIFICATION GUIDELINES FOR MODULAR BUDGETS (and Non-Modular Personnel Justification Sections)

(Source: *NIH SF424 (R&R) Application Guide*)

"List all personnel, including names, percent effort (use the Person Months metric), 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, 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.

PERSONNEL JUSTIFICATION TEMPLATE

Personnel Justification

Principal Investigator, Program Director, or Project Director (PD/PI):

"The individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. The applicant organization may designate multiple individuals as program directors/principal investigators (PD/PIs) who share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple PD/PIs are named, each is responsible and accountable to the applicant organization, or, as appropriate, to a collaborating organization, for the proper conduct of the project or program including the submission of all required reports. The presence of more than one PD/PI on an application or award diminishes neither the responsibility nor the accountability of any individual PD/PI."

Senior/Key Personnel:

"The PD/PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition. Consultants and those with a postdoctoral role also may be considered senior/key personnel if they meet this definition. Senior/key personnel must devote measurable effort to the project whether or not salaries or compensation are requested. "Zero present" effort or "as needed" are not acceptable levels of involvement for those designated as Senior/Key Personnel."

Other Significant Contributors:

"Individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (i.e., person months) to the project. These individuals are typically presented at "effort of zero person months" or "as needed." Individuals with measurable effort may not be listed as Other Significant Contributors (OSCs). Consultants should be included if they meet this definition."