SPORE in Pancreatic Cancer
Sept 2018 Competitive Renewal
REQUEST FOR PROJECTS

The UNMC SPORE in Pancreatic Cancer will submit a competitive renewal application in September 2018. With this RFP, potential projects will be accepted for consideration for inclusion in the competitive renewal.

All SPORE projects must be translational. Translational Research uses knowledge of human biology to develop and test the feasibility of cancer-relevant interventions in human 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, biological agents, and/or other methodologies applicable to the prevention, early detection, diagnosis, prognosis, and/or treatment of cancer.

In every SPORE project, the development of new cancer-relevant interventions should include both a laboratory component and a human endpoint that must be reached during the project period of the grant. All SPOREs must include at least one project that proposes a clinical trial which can serve as the required human endpoint for that proposed project

> *Note:* An IND-directed toxicology study can serve as a human endpoint, but is not sufficient to satisfy the clinical trial requirement. Inherent in this process is the interdependence between investigators conducting basic and applied research. Clinical and/or epidemiological research that does not include a wet laboratory or imaging component is not considered translational for the SPORE.

SPORE translational research projects may involve the use of any cellular, molecular, structural, biochemical, and/or genetic experimental approaches. By this definition, SPORE projects are permitted to move not only in the forward direction, toward clinical trials and studies in areas of prevention, early detection, treatment, development of biomarkers, and population science, but also in the reverse direction, using human biospecimens, often from clinical trials, to study new phenomena, to optimize previous findings, or to develop new hypotheses based on results from human studies.

In each SPORE project, at least one of the following types of human endpoints should be proposed:

- Early phase clinical trials of new investigational drugs, biologics, experimental procedures, medical devices, or combinations;
- Early phase clinical trials of new combinations or new uses of the Food and Drug Administration (FDA)-approved agents and devices;
- Discovery and development of biomarkers, only when measurements are made in human specimens, or directly in human subjects;
- Laboratory studies that begin with an observation in the clinic and use human specimens to generate new clinical hypotheses;
- Population, behavioral, or psychosocial studies, when these studies address mechanistic aspects of the biology of the disease;
- 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 endpoint is included in the specific aims.
- Investigational new drug (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.

Experiments using cell lines, xenografts, patient-derived xenografts (PDX), organoids, paired germline samples, or engineered tissues, may be important to the translational studies proposed and are encouraged, but are not sufficient to meet the human endpoint requirement.

SPORE applications are encouraged to include the following:

- Research and patient advocates with a collective patient perspective to be an integral component of the SPORE Program
- Early Detection, Prevention, or Population Science (EPPS) projects. [See EPPS definition in Part 2, Section I, of the SPORE FOA.]
- Research projects that bring together investigators from multiple institutions to facilitate the development of large-scale team-based projects.

Applications should be NIH R01-style project applications. All instructions in the SF424 (R & R) Application Guide must be followed, with these additional instructions:

- Each project is required to include both basic and applied/clinical co-leaders who will use their combined expertise to design and implement the project
- Each co-leader must commit individually to a minimum of 0.6 person months (PM) of effort. It is not necessary that the co-leaders commit equal amount to the project, and this minimum effort may not be reduced for the duration of the SPORE, if funded.
- Arial 11 point font or larger is required, margins must be at least 1/2 inch on all sides, and font color should be black.

SPORE Project Applications should include the following:

1. *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.*

2. *Research Strategy* (12 pages). Organize the Research Strategy, using the instructions given below, including the Preliminary Studies. Start each section with the appropriate section heading. Experimental details should be cited using the Bibliography and References Cited section and need not be detailed in the Research Strategy.

   a) Significance
   - Explain the importance of the problem or the critical barrier to progress in translational cancer research that the proposed project addresses.
   - Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.
   - Explain how the proposed translational science project will improve scientific knowledge, technical capability, and/or clinical practice in the organ site(s) studied.
   - Describe how the concepts, methods, technologies, treatments, services, or preventive interventions that drive organ site research will be changed if the proposed aims are achieved.

   b) Innovation
   - Explain how the project challenges and seeks to shift current translational research or clinical practice paradigms.
   - Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).
   - Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.

   c) Approach
   - Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted. Emphasize how the experimental design and methods proposed will achieve robust and unbiased results.
   - Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the specific stated aims and the overall aim of reaching a human end-point within the 5-year funding period.
   - If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.
   - Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
   - *Preliminary Studies for New Projects:* For new projects, include information on Preliminary Studies as part of the Approach section. Discuss the preliminary studies, data, and/or experience of the co-leaders of the project that are pertinent to the project. Discuss any preliminary plans for vertical and/or horizontal collaborations in the SC section of the Overall component.

3. Bibliography and References Cited

4. NIH Biosketch, on the current NIH biosketch template (OMB No. 0925-0001 and 0925-0002 (Rev. 09/17 Approved Through 03/31/2020) for Co-Project Leaders.

All applications must be emailed as a single, complete PDF to Cindy Plate (cjplate@unmc.edu) with a copy to Tony Hollingsworth (mahollin@unmc.edu) by 4:00 P.M., Friday, June 15, 2018. (NO EXCEPTIONS WILL BE MADE). ***Please include "SPORE Project"*** and the last name of the Principal Investigator in the subject line of the email. You will receive a confirmation by Monday, June 18.

If you have any questions, please contact Tony Hollingsworth, 402-559-8343, (mahollin@unmc.edu), or Cindy Plate, 402-559-4192, (cjplate@unmc.edu).

ADDITIONAL INFORMATION *and resources*

Translational Research Program (TRP) – National Cancer Institute TRP page

PAR-18-313 – Funding Opportunity Announcement for Specialized Programs of Research Excellence (SPOREs) in Human Cancers for Years 2018, 2019, and 2020 (P50 Clinical Trial Required)