NEW FUNDING OPPORTUNITY

Second Round of Padres Pedal the Cause Grants
MCC only grants allowed; Clinical Trial support also allowed!

PADRES PEDAL THE CAUSE
2018 Moores Cancer Center Clinical and Translational Cancer Research Awards

Padres Pedal the Cause Mission:
To provide funding for the finest collaborative research teams at UC San Diego Moores Cancer Center, the Salk Institute for Biological Studies, Sanford Burnham Prebys Medical Discovery Institute and Rady Children’s Hospital San Diego. Padres Pedal the Cause desires to fund research that will lead to increased survivorship and ultimately, cures for cancer.

In the past five years, Padres Pedal the Cause has donated more than $7.1 million to fund 42 local cancer research projects in San Diego. Padres Pedal the Cause provides funding for all types of cancer research, with grants awarded fund to explorative discovery research.

Request for Applications (RFA)
Deadline: Friday, August 17, 2018 @ 5:00 PM (PST)

PURPOSE:
Nearly $1.5 million of proceeds from Padres Pedal the Cause are available to faculty members of the UC San Diego Moores Cancer Center to stimulate scientific collaboration and innovative translational cancer research in the basic, clinical, and population (public health) sciences. This RFA seeks applications in basic science, translational and public health research across a wide spectrum of disease-focused areas to encourage greater breadth and depth related to the prevention, diagnosis, or treatment of cancer involving patients and populations. The research supported through this mechanism must have translational potential or significance.

This RFA solicits 2 types of awards:
1. Translational Research Award
2. Investigator-Initiated Clinical Trial Award

Investigators applying for funding may only submit applications for 1 award type. Priority will be given to proposals that have a high likelihood of leading to extramural research funding, provide new approaches to important clinical or population/community challenges, or offer a clear route to a clinical trial and/or include the protocol for the investigator-initiated clinical trial based on translation of scientific discoveries from Moores Cancer Center members. Collaborations with C3 members from C3 Institutes (Salk and Sanford Burnham Prebys Cancer Centers) and from UC San Diego-affiliated institutions (Rady Children’s, SDSU, JCVI, LJI, SIO) are encouraged but not required.
Participation Requirement for ALL Padres Pedal the Cause Grant Awardees:
PIs shall participate in the next Padres Pedal the Cause (https://www.gopedal.org) as a Team Captain, rider, spinner, runner, walker, volunteer, or virtual rider. PIs shall present at the annual C3 Scientific Retreat the following year or as requested.

FUNDING:

1. Translational Research Award
   Awards up to $125K for one (1) year are expected to be funded in 2018. If an investigator-initiated clinical trial translating proposed research is scheduled to begin within the funding period, a full protocol draft and clinical trial budget and may be included with a request for year 2 funding.

2. Investigator-Initiated Clinical Trial Award
   Awards up to $150K/year for two (2) years are expected to be funded in 2018. Second year of funding is contingent upon meeting 50% accrual goals for year 1. Full clinical trial budgets should be included, and additional funding may be considered in special cases.

BUDGETARY GUIDELINES:
The budget may include partial salary support for faculty investigators, trainee investigators (graduate students/postdocs), laboratory technicians, protocol writer and other related study expenses. Also included: shared resources, publication fees, and supplies. Travel, professional meeting fees, salary support for administrative personnel, and equipment are excluded. Award funds may not be applied to costs that are reimbursable by a third-party payor or cost shared by another sponsor. No IDC allowed.

PROPOSAL REQUIREMENTS FOR ALL SUBMISSIONS:
A. Scientific Abstract (up to 250 words): The purpose of the Project Summary/Abstract is to describe succinctly every major aspect of the proposed project. It should contain a statement of objectives and methods to be employed.

B. Lay Abstract (up to 250 words): Describe in lay language the potential impact of the project on cancer treatment, prevention and diagnosis in the short and long term.

C. Specific Aims (up to 1 page): The purpose of the Specific Aims is to describe concisely and realistically the goals of the proposed research and summarize the expected outcome(s), including the impact of the proposed research will exert on the research fields involved. The Specific Aims should include goals, hypotheses, role of each PI and senior/key personnel, and expected outcomes.

D. Translational Research Award Research Strategy (up to 3 pages, excluding references): This section should not exceed 3 pages including preliminary data, and should address the following: Significance, Innovation and Approach. The Significance should explain the importance of the problem or describe the critical barrier to progress in the field that is being addressed. Explain how the proposed research project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved. The Innovation should explain how the application challenges and seeks to shift current research or clinical practice paradigms. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions. The purpose of the Approach is to describe how the research will be carried out. Applications must propose the use of institutional core facilities, if applicable and available. This section is crucial to how favorably an application is reviewed.

OR

Investigator-Initiated Clinical Trial Award Clinical Protocol: The full protocol should be submitted. The protocol should include a detailed timeline and accrual milestones. The protocol should also include a biostatistics summary to describe how the proposed design and methods will achieve robust and unbiased results.
E. **Biosketches**: A biosketch for each PI and senior/key personnel (NIH Standard 5-page Biosketch) with relevant recent publications and other current and pending support should be included in the application.

F. **Budget and Budget Justification** (No page limit): The purpose of the budget and justification is to present and justify all expenses required to achieve project aims and objectives. Please indicate performance period for the project. Indicate if cost sharing will be provided from other funding sources in order to complete the aims of the project in your budget justification.

G. **Translational Research Award Biospecimen Request Form**: For proposals utilizing Biorepository specimens, a Biospecimen Request Form must be completed. The Biorepository and Tissue Technology Shared Resource website provides additional detail about resources that are available. Please contact the Biorepository Manager (Sharmeela Kaushal, PhD) at ccbr@ad.ucsd.edu. Investigator must establish study feasibility (e.g., availability of suitable samples) to be included with the application.

**ADDITIONAL REQUIREMENTS FOR INVESTIGATOR-INITIATED CLINICAL TRIAL AWARD**

H. **Disease Team Approval**: Any project proposing to study patients at UC San Diego Moores Cancer Center must have signed approval of the respective Disease Team Leaders declaring that the study is feasible based upon the proposed patient population, needed accrual, and competing funded studies. Where appropriate, physicians overseeing the care for these patients should be considered for co-investigator status.

I. **Protocol Review and Monitoring Committee Approval**: For proposals involving a clinical trial, a full protocol approved by the Protocol Review and Monitoring Committee must be included with: (a) intervention(s) to be used, reasons for the selection of intervention(s), and mode(s) of delivery; (b) study design, treatment group(s), trial size, and inclusion/exclusion criteria; (c) control group(s) if applicable; (d) outcome measures; (e) data analysis plan if applicable; and (f) detailed timeline with accrual milestones. Awards can be leveraged with other funding sources for the clinical trial provided that feasibility (e.g., drug availability, accrual and timeline) is clearly outlined in the application.

**FORMAT SPECIFICATIONS:**
All applications must adhere to the following guidelines:
- Use Arial font 11 points or larger
- Use at least one-half inch margins (top, bottom, left and right) for all pages
- The application must be single-spaced and saved as a PDF
- Consecutively number pages in the Research Proposal
- As applicable, figures or other materials must be inserted directly into the body of the application
- No appendices

**APPLICATION GUIDELINES:**
The deadline is 5:00 PM PST, **FRIDAY, August 17, 2018**. The earliest starting date is **November 1, 2018**. All applications (pdf) must be submitted electronically via the MCC web-based pilot project review system called WebGAAS: http://moores.ucsd.edu/Admin/grants-in-aid.asp. The grant forms are downloaded from here. There are different grant forms for translational and investigator initiated trial applications. Once an application has been submitted electronically via WebGAAS, it cannot be changed.

**HUMAN AND ANIMAL SUBJECTS, SAFETY, AND ENVIRONMENTAL HEALTH ISSUES:**
Pending IRB or IACUC approval, copies of IRB or IACUC approval must be submitted prior to activation of the grant award.

**EVALUATION CRITERIA:**
The Review Committee will conduct an NIH-style internal peer review of applications. The goal of the RFA is to advance our understanding of cancer and foster the development of new collaborative approaches toward cancer prevention, control, and treatment. Reviewers will aim for distribution of funds across a variety of research areas and disease teams. The Review Committee will discuss the following aspects of each application:
• Fulfillment of the requirements and eligibility criteria of this RFA
• **Significance:** Does the proposal address an important problem? Will the proposal provide a better understanding of the disease, influence SOC, develop a new prevention or therapy?
• **Investigators:** Are investigators qualified to conduct project?
• **Approach:** Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Are the aims original and innovative
• **Feasibility:** Do the research design and methods appear appropriate and reasonable, and can the aims be achieved within one (1) year? Is the project likely to lead to external grant funding?
• **Human Subjects:** Are there any major ethical concerns surrounding human subjects?
• **Participation in Padres Pedal the Cause**

**USE OF FUNDS:**
The funds are to be used in general agreement with the research budget plan submitted with the application, but the Center will allow the investigator to re-budget up to 10%, in accordance with his or her needs, without requiring a budget resubmission. A no-cost extension beyond the grant funding period is not automatic and must be requested a minimum of 60 days before the project end date. A progress report must be completed prior to approving a no-cost extension.

**PROGRESS REPORTING AND CITATION REQUIREMENTS:**
Detailed progress reports are required **semi-annually** for as long as the project is active. All progress reports must include accrual data and interim analysis. Disbursement of second year funding is contingent upon meeting 50% accrual goal at end of year 1 and the timely submission of a satisfactory and complete annual progress report. **Investigators who do not meet accrual goals will be required to provide a detailed justification or will be responsible for return of full amount of the award.**

A final progress report is due 60 days after the project end date and must include a description of future extramural grant applications to be submitted.

Investigators are expected to publish original article at conclusion of the project. All publications (as well as posters and abstracts at scientific meetings) that result from the support provided by this award **must** acknowledge that support in writing as follows: **“Padres Pedal the Cause #PTC2018.”**

**EARLY TERMINATION OR TRANSFER OF RESEARCH FUNDS:**
If the grantee decides to discontinue the research project or leave UC San Diego, the Cancer Center must be notified immediately and the project will be terminated.

**GRANTEE PROGRESS/IMPACT REPORTS:**
- The **Progress Report** form will be sent to each PI six (6) months **after the beginning** of the funding period.
- The **Impact Report** form will be sent to each PI one (1) month **after the end** of the funding period.

Each form must be completed and returned **within one (1) week** to Danielle McLaughlin (d4mclaughlin@ucsd.edu) for review by the Padres Pedal/C3 Steering Committee. The synthesis of annual **Impact Reports** will be the main mechanism for the public reporting of Padres Pedal fund stewardship as well as institutional and community marketing purposes.

**INQUIRIES:**
Please direct inquiries to Sylvia Sedman, Manager of the Office of Grant Development.

Email: ssedman@ucsd.edu
Phone: (858) 657-6952