

**2020 Padres Pedal the Cause
Investigator-Initiated Clinical Trial and Team Science Awards
MCC only grants allowed!**

Request for Applications (RFA)

Deadline: Monday, November 2, 2020 @ 5:00 PM (PST)

Padres Pedal the Cause Mission: A World Without Cancer

We're on a mission to accelerate cures for cancer by funding collaborative research and clinical trials among San Diego's top cancer research and treatment centers: Moores Cancer Center at UC San Diego Health, the Salk Institute for Biological Studies, Sanford Burnham Prebys Medical Discovery Institute, and Rady Children's Hospital San Diego.

Cancer is the #1 cause of death in San Diego and #2 cause of death in the United States. 1-in-3 of us will be diagnosed with cancer in our lifetime. In some way, this disease will touch all of our lives: every person, every family, every community.

Since its inception, Padres Pedal the Cause has donated more than \$10 million to fund 53 local cancer research projects in San Diego, including five clinical trials. We provide funding for all types of cancer research, with grants awarded to fund explorative discovery research that target specific cancer types and universal studies that benefit multiple kinds of cancer and tumors.

It is our goal that research funded by Padres Pedal the Cause will lead to increased survivorship and ultimately, cures for cancer.



PURPOSE:

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 clinical or team science 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 clinical/translational potential or significance.

This RFA solicits proposals for 2 types of awards:

1. Investigator-Initiated Clinical Trial Award

One (1) award up to **\$150K/year for two (2) years**, is expected to be funded from this Fall 2020 RFA. The second year of funding is contingent upon meeting 50% accrual goals for year one. Full clinical trial budgets should be included. Collaborations with C3 members from other C3 Institutes (Salk, Sanford Burnham Prebys Cancer Centers) and from UC San Diego-affiliated institutions (Rady Children's, LJI, JCVI, SDSU, SIO) are **encouraged but not required**.

2. Team Science Award

One (1) award up to **\$200K/year for one (1) year** is expected to be funded from this Fall 2020 RFA. The successful team, a multidisciplinary, synergistic team of expert investigators, will develop a collaborative, translational, interdisciplinary cancer research program that will result in new and diverse approaches to the prevention, early detection, diagnosis, and/or treatment of cancers. The **Team Leader must be a UC San Diego Moores Cancer Center faculty member**. **Project Leaders** can be MCC faculty or MCC members from C3 Institutes (MCC, Salk, Sanford Burnham Prebys Cancer Centers) and/or from UC San Diego-affiliated institutions (Rady Children's, LJI, JCVI, SDSU, SIO). **There must be a minimum of 3 projects, and the Team Leader must be a PI or Co-PI on at least one project**. The proposed research must be designed to address significant problems in cancer through basic, translational, clinical, or population science research, with the **EXPLICIT GOAL of submission of a multi-project grant application (such as a P01, SPORE, etc.)**. The Team Science proposal must have a central, well-defined research focus or objective, with interrelated research projects, each capable of standing on its own scientific merit but complementing one another, and a Team Leader with the expertise to synergize the work across projects. The individual research projects should reflect a distinct, separate, scientifically meritorious research effort led by independent investigators, the Project Leaders. In addition, the individual projects should

be clearly interrelated and synergistic so that the research ideas, efforts, and outcomes of the Team Science project as a whole will offer a distinct advantage over pursuing the individual projects separately.

DEFINITIONS:

Team Leader - The Team Leader is the person responsible for the scientific and technical direction of the proposed research project, contractual and financial obligations, and other organizational assurances/certifications. The Team Leader must ensure that the Team complies with the terms and conditions of the award and will be the primary contact person for MCC grants administration and Padres Pedal the Cause. The Team Leader must be an MCC faculty member.

Project Leaders - Project Leaders are senior investigators (members from a C3 institution [MCC, Salk, SBP] or an affiliated institution [e.g., Rady Children's, LJI, JCVI, SDSU, SIO]) who will lead a component(s) or subproject(s) of the Team research project.

Principal Investigators and Co-Principal Investigators (PIs and Co-PIs) applying for funding may submit an application for *only 1 award type*, and PIs/Co-PIs who have received *2019 Team Science or Clinical Trials (IIT) PEDAL* funding are *ineligible* to apply (see page 6). Priority will be given to proposals that have a high likelihood of leading to extramural research funding (with a stated plan for such), provide new approaches to important clinical or population/community challenges, and/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 the San Diego scientific community.

BUDGETARY GUIDELINES:

The budget may include partial salary support (at the NIH cap) 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 to professional meetings, professional meeting fees, salary support for administrative personnel, and equipment are excluded.** Travel related to development of team science grant applications such as to the NCI for meeting with the program officer(s) or travel for external advisors is allowable. 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.** *If a non-MCC institution is included in the budget, a letter of their institutional commitment to waiving IDC must be included with the application.*

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. **Research Strategy** (up to **3 pages for IIT** and **5 pages for Team Science, excluding references**):

For Investigator-Initiated Clinical Trial Award-This application must include the full Clinical Protocol (uploaded separately). The Research Strategy section should not exceed 3 pages and should address the following: Significance, Innovation, Approach, Timeline, Accrual Milestones, Biostatistics Summary. 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 must also include a detailed Timeline, Accrual Milestones, and a Biostatistics Summary to describe how the proposed design and methods will achieve robust and unbiased results.

For Team Science Award-This section should not exceed 5 pages and must include **EXPLICIT PLANS for submitting a multi-project grant application (e.g., P01, SPORE, etc.)**. The 5 pages should be organized as a 1 page overall summary of the team science grant and up to 4 pages for the description of each project, core and component that will be included in the submission. The project descriptions 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.

- E. **Biosketches:** A biosketch for each PI/Project Leader 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. A budget justification and summary for all major budget categories (e.g., salary, etc.) must be provided for each site. The application must also include a composite budget summary for all budget categories. 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. **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 cabr@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 or Rady Children's Hospital *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 **Monday, November 2, 2020, 5:00 PM PST**. The earliest starting date is **December 1, 2020**. 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 Investigator-Initiated Trial and Team Science 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.

ELIGIBILITY RULES:

1. A PI/Co-PI may **submit only one (1) application in response to this RFA**.
2. PIs/Co-PIs who received *2019 Team Science or Clinical Trials (IIT) Padres Pedal the Cause* awards are not eligible to apply. **See page 6 of this RFA for a list of ineligible PIs/Co-PIs.**
3. When applicable, budget allocation for **each** institution must not be less than 30%.
4. **REQUIRED** to be a participant in the 2021 Padres Pedal the Cause as a Team Captain, rider, spinner, runner, walker, volunteer, or virtual rider.
5. **REQUIRED** to serve as a reviewer for Pedal grants over the next 24 months, as requested.

*****If you have any questions about eligibility of the PI/Co-PIs, please contact Angela Ballantyne, PhD at aballantyne@health.ucsd.edu*****

Participation Requirement for ALL Padres Pedal the Cause Grant Awardees:

PIs are required to participate in the **2021** 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 MCC Scientific Retreat the following year or as requested.

EVALUATION CRITERIA:

The MCC Pilot Grants Program will appoint a Review Committee to conduct an NIH-style 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, diagnosis, control, and treatment and to foster the development of new team science approaches across the C3 member institutions. The Review Committee will discuss the following aspects of each application:

- Scientific merit of the proposed research project and clinical/translational nature of the research, e.g., plan for translating the work from the laboratory to the clinic or community;
- Significance of the proposed research, i.e., whether it addresses a critical need for rapid progress beyond current approaches;
- Novelty of the hypothesis or methodology;
- Degree to which the studies will have a positive therapeutic impact on the detection, treatment or prevention of cancer or pre-cancer;
- Likelihood that the project will lead to significant follow-on funding and/or return on investment (including, for Team Science projects, an explicit and well-justified plan for future submission of a multi-project grant (e.g., P01, SPORE, etc.).

- A clear commitment by grant awardees that all data resulting from their work will be available to the scientific community at large at the earliest opportunity;
- Likelihood that the research project will achieve its stated goals given the budget requested, institutional environments, and other resources available and lead to extramural funding;
- Whether the studies are designed to capitalize upon the unique populations and environments, specialized expertise, new concepts and perspectives, innovative methodologies, and/or emerging technologies that are available due to the multi-institutional collaboration (if applicable);
- Whether adequate institutional and/or financial support exists to sustain the research project;
- Fulfillment of the requirements and eligibility criteria of this RFA.

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, when applicable, 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 the full amount of the award.**

A final progress report (Impact Report) is due 30 days after the project end date and must include a description of future extramural grant applications to be submitted.

Investigators are expected to publish an original article(s) at the conclusion of the project. All publications and presentations (as well as posters and abstracts at scientific meetings) that result from the support provided by this award **must** acknowledge the support in writing as follows: **“Padres Pedal the Cause #PTC2020.”**

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. The funds are non-transferrable.

GRANTEE PROGRESS/IMPACT REPORTS:

- The **Progress Report** form will be sent to each PI six (6) months after the beginning of the funding period (for 2-year IITs, these reports will be sent at the 6, 12, and 18 month marks).
- 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 two (2) weeks to Angela Ballantyne (aballantyne@ucsd.edu) for review by the MCC Pilot Grants Program 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 Angela Ballantyne, PhD, Director of Research Development and Collaboration. Email: aballantyne@health.ucsd.edu; Phone: (858) 822-0182

****Please see the following page for a list of ineligible PIs/Co-PIs****

Based on a 2019 Team Science or Clinical Trial (IT) PEDAL award, the following individuals are **NOT** eligible to be **PI or Co-PI**; however, they may be a co-investigator:

Parsons, JK
Reya, T
Ball, E
Bejar, R
Lowy, A
Newton, A