Siteman Investment Program (SIP) Awards
Request for Applications (RFA)

A. Deadlines

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<th>Biannual announcements:</th>
<th>January 15</th>
<th>July 15</th>
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<td>Statement of Intent due by 4:00 pm CST:</td>
<td>March 1</td>
<td>September 1</td>
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<td>Full applications due by 4:00 pm CST:</td>
<td>April 1</td>
<td>October 2</td>
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<td>Start dates:</td>
<td>July 1</td>
<td>January 1</td>
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B. Purpose

- To provide pilot funding for cancer-related research, including, but not limited to: discovery, diagnosis, imaging technology, treatment, and prevention and early detection in clinical and community settings
- Advance the most promising ideas that will allow physicians to predict, prevent, diagnose, treat, or cure all types of cancers more effectively and with fewer or no side effects, for example, by tailoring therapies to a patient’s individual genetic makeup or the biology of their disease
- Accelerate discoveries to test and verify pioneering options for fighting cancer and translate clinical findings into groundbreaking, practical applications
- Accelerate dissemination and implementation research that moves evidence based cancer practices into clinical and community settings
- Catalyze discoveries by building bridges among disciplines and researchers in St. Louis
- Produce data that provide the basis for future applications (such as R01s, R21s, DOD, SPOREs, PPGs, etc.) or the opportunity for business creation and venture funding

C. Eligibility

- You must have a full-time faculty appointment at Washington University or Saint Louis University.
- The primary PI submitting the application must be a Siteman Cancer Center member. Questions regarding membership should be directed to Carrie Wehking, wehkingc@wustl.edu.
- A faculty member currently funded in the role of PI by a SIP Pre-R01 or Multi-PI Pre-R01 is not eligible to submit a Pre-R01 or Multi-PI Pre-R01 unless (1) their current award will end by the scheduled start date; or (2) the award is in a no-cost extension.
- A faculty member may be the PI on one (1) Pre-R01 or Multi-PI Pre-R01 submission per cycle. For example, a PI on a Multi-PI Pre-R01 application would not be eligible to submit a Pre-R01 application. A PI is allowed to be a co-investigator, or consultant on any number of submissions.
- Any faculty member may submit a Pre-R01 or Multi-PI Pre-R01 AND participate as PI or project PI/leader on a Pre-SPORE/PPG(s), as long as the projects are scientifically unique. Please note that SIP will not fund the same science multiple times. A project submitted under a Pre-SPORE/PPG application will not be considered for funding as a Pre-R01 or Multi-PI Pre-R01 in the same cycle.
- Faculty requesting salary support on a SIP application are strongly encouraged to participate in the Pedal the Cause event on September 23-24, 2017. Pedal the Cause is one of the largest donors to the SIP and their organization solely exists to fund cancer research grant applications at Siteman Cancer Center and St. Louis Children’s Hospital. There are many ways to participate in Pedal the Cause, including as a rider, virtual rider, or volunteer. Please visit http://pedalthecause.org for more information.

D. Award Information

Assumptions

- Total awards are dependent upon available philanthropic dollars
  - The number of awards and the award amount may increase or decrease each year dependent upon SCC philanthropic dollars received
- Total awards are dependent upon scientific merit
The number of awards and the award amount may increase or decrease each year dependent upon scientific merit of the projects presented at each study section.

There are three types of research mechanisms available:

1a. Pre-R01 Program for WUSTL Medical School faculty only
   • Used to support a discrete, specified hypothesis driven research project
   • Provides support for a variety of cancer-related types of projects, including: pilot or feasibility studies; collection of preliminary data; secondary analysis of existing data; small, self-contained research projects; development of new research technology; etc.
   • Total project period may not exceed 2 years
   • Combined budget for direct costs for the total project period may not exceed $200,000

1b. Pre-R01 Program for SLU Consortium and WUSTL Danforth Campus faculty only
   • Used to support a discrete, specified hypothesis driven research project
   • Provides support for a variety of cancer-related types of projects, including: pilot or feasibility studies; collection of preliminary data; secondary analysis of existing data; small, self-contained research projects; development of new research technology; etc.
   • Total project period may not exceed 2 years
   • Combined budget for direct costs for the total project period may not exceed $200,000

2. Multi-PI Pre-R01 for all WUSTL/SLU cancer researchers
   • Used to support a discrete, specified hypothesis driven research project
   • Provides support for a variety of cancer-related types of projects, including: pilot or feasibility studies; collection of preliminary data; secondary analysis of existing data; small, self-contained research projects; development of new research technology; etc.
   • Total project period may not exceed 2 years
   • Combined budget for direct costs for the total project period may not exceed $400,000

3. Pre-SPORE/PPG Program for all WUSTL/SLU cancer researchers
   • Encourages new, exploratory and developmental research projects by providing support for the early stages of project development. May be used for pilot and feasibility studies and device development. Designed to permit early peer-review of the rationale for the proposed clinical trial, and support development of essential elements of a clinical trial.
   • Total project period may not exceed 2 years
   • Combined budget for direct costs for the total project period may not exceed $800,000
   • PIs of multi-project awards are allowed to apply for interim competitive renewal funding. For interim funding, only 1 year may be requested. Combined budget for direct costs for the 1 year may not exceed $400,000. The following documents are required with submission:
     o Submitted Scientific Report to date
     o Internal & External Advisory Board Reports

The following criteria is applicable to all research awards:

• Project(s) must be clearly cancer-focused
• Project(s) should utilize at least one Siteman Cancer Center Shared Resource (Core), unless core services are not relevant to your project. [http://www.siteman.wustl.edu/ContentPage.aspx?id=229](http://www.siteman.wustl.edu/ContentPage.aspx?id=229)
• PRMC, IRB or animal studies must be submitted before the award start date.
• Project must start within six months post Notice of Award or funding will be rescinded. PIs can re-compete in the next funding cycle.

E. Submission Guidelines

Pre-submission Guidelines:
A brief statement of intent (SOI) is required and due to Jaclyn McGuire (mcguirej@wustl.edu) by 4:00pm CST on the due date. The SOI should be a Word document and include the following information:
1) Name of the PI or PIs, in the case of a Multi-PI project;
2) Project title;
3) Abstract;
4) Mechanism for which you are applying

Submission Guidelines:
Combine all documents into one PDF document and submit your application by 4:00pm CST on the deadline, via proposalCENTRAL. Note: The signature page generated by proposalCENTRAL is not required.
Formatting:
- Applicants must use the NIH PHS 398 forms, unless otherwise indicated. Applicants must follow the NIH guidelines when completing the forms. NIH forms can be found at: http://grants.nih.gov/grants/funding/phs398/phs398.html
- Please type your name (last name, first initial) in the header of each page. Use Arial 11 pt font for text.
- It is better to print to PDF versus saving to PDF. The applicant is responsible for previewing the final document in proposalCENTRAL and ensuring that no errors occurred in compiling the PDF application.

Required Application Components:
1. Siteman Cancer Center Cover Sheet (Download from website – Updated July 2016)
   - Due to the nature of the sponsor reporting process, SCC requires a description of your research project written in “lay” language. Please do not use your grant application Project Summary. The purpose of the lay language summary is to provide a clear overview of the research in straightforward, non-technical language to be shared with the sponsors, donors, the general public, and the media. Do not exceed 150 words.
1a. Re-submissions only: response to prior SIP critique (1 page maximum)
   - Resubmissions are encouraged. Please include a one-page response to the prior critiques. This page should be inserted directly after the Siteman Cancer Center Cover Sheet.
2. NIH Face Page (PHS 398 Form Page 1)
3. Project Summary and Key Personnel (PHS 398 Form Page 2)
4. Budget Pages (PHS 398 Form Page 4 and 5)
   - A detailed budget justification is required. (See allowable expenditures below)
   - For pre-SPORE/PPG applications, please complete Form Pages 4 and 5 for each project
5. NIH Biosketches for all key personnel (Instructions and Samples)
   - Please use NIH guidelines; the “new” NIH format applies to this cycle.
6. Specific Aims and Research Strategy
   a. Specific Aims (1 page maximum)
      - State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that results from the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.
   b. Research Strategy
      - Pre-R01/Multi-PI Pre-R01 page limit: 6 pages maximum
      - Pre-SPORE/PPG page limit: 12 pages maximum
      - Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section.

1) Significance
   - Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
   - Explain how the proposed 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.

2) Innovation
   - 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/methodologies, instrumentation, or interventions.

3) 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.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- 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.

7. Bibliography and References Cited (2 page maximum)
8. Multi-PI Leadership Plan (if applicable; 2 page maximum)
   - For applications designating multiple PIs, a leadership plan is required. The rationale for choosing a multiple PI approach should be described, including the added benefit of this approach. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. Each PI must bring key scientific knowledge and responsibilities. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PIs, including responsibilities for human or live vertebrate animal subject studies as appropriate. Do not submit a leadership plan if you are not submitting an application with multiple PIs.

9. Plans for Subsequent Funding (1 page maximum)
   - Discuss how the findings from your project will be used to write a proposal for subsequent NIH/NCI funding or other funding. In this regard, applicants should list potential aims for a NIH proposal. This section is an important criterion for award selection by SCC. If the SIP application is in response to a submitted, but not funded, NIH application, you have the option to include the Summary Statement as a supporting document in this section (not included in the page limit).

10. SCC Shared Resource/Core Utilization (1 page maximum)
   - Describe Siteman Shared Resource (Core) usage.

11. Compliance Document(s)
   - Include a page indicating the status of all applicable institutional approvals as listed on the cover sheet (e.g., animal, IRB, PRMC). Include approval letters or a brief summary of the plan and timeline. Funds will not be released without documentation of required approvals.

12. Letter(s) of Support
   - Include a letter of support from the director(s) for each Siteman Shared Resource you will be using in your research. You may also include other letters of support for the project from appropriate sources (division chief, department chair, collaborators, mentor, etc.)

Please Note: No appendix materials allowed.

Applications must include all sections. Late and/or incomplete applications will not be accepted. Each cycle, applications are not scientifically reviewed because they have omitted required documents. Please submit your application at least 48 hours in advance of the deadline if you would like an administrative review prior to the deadline.

Budget:
Facilities and Administrative (F/A)/Indirect Costs: Do not include indirect costs at time of submission. If appropriate, based on the funding source, indirect costs will be added post-award.
Expenditures Allowed:

- Salary support for investigators and other relevant faculty collaborators or staff. The NIH salary cap should be used in the budget.
- Research supplies
- Per diem charges for patients, if part of a clinical study, not reimbursable by standard payment terms
- Technical assistance
- Stipends for graduate students and postdoctoral assistants, if relevant to the application; must be justified in the budget
- Domestic travel only when necessary to carry out proposed research
- Computational services
- Other expenses such as lab and core fees, pathology, imaging, etc.
- Consultants and sub-contracts. Siteman recognizes that certain projects may require unique expertise not immediately available at Siteman, WUSM, SLU, or BJH. The application should clearly address this deficit and describe those aspects of the project to be contributed by external consultants and subcontractors. Projects with significant off-site effort will be less competitive for funding.
- Non-office equipment over $5,000 intended for the use in a SIP cancer-related research project must include a detailed justification.
- Technology needed in order to design, build, test or facilitate a new device focused on cancer (e.g. new imaging modalities or other biomedical engineering devices) is allowable and not limited to a dollar amount. However, clear justification for the purchase must be provided in the budget justification.
- If you plan to request funding for support for investigators outside of WU or SLU, please contact Jaclyn McGuire prior to submission.
- Publications costs not to exceed $1,000 across the total project period.

Expenditures NOT Allowed:

- Secretarial/administrative personnel salary support
- Office equipment and supplies
- Computer and equipment maintenance fees
- Tuition
- Travel and/or registration/related fees for conferences. Foreign travel and/or any travel not essential to carrying out the proposed research
- Honoraria and travel expenses for visiting lecturers
- Dues and membership fees in scientific societies
- Office and laboratory space
- Non-medical services to patients

F. Terms of the Award

- Acceptance of funds implies a firm commitment to provide a first year progress report by the deadline outlined in the NOA and subsequently, an annual update for a five-year follow-up period. Second year funding is contingent on submission of a progress report by the stated deadline. Awardees who do not reply to five-year follow up requests will jeopardize future SCC awards.
- Siteman expects that the grantee will completely utilize the full amount of funding during the term of the award. No-cost extensions are discouraged but will be considered with compelling justification. All unspent funds at the end of the grant period will be returned to the sponsor.
- All awards must have appropriate institutional approvals (e.g. SCC PRMC, HRPO, Animal Studies, Radiation Safety, etc.) before funds will be allocated.
- All awards, publications and presentations must acknowledge Siteman Cancer Center and the indicated sponsor(s) identified in the NOA.
- Acceptance of funds implies a firm commitment to provide the sponsor access to meet the team, give talks to the public and tours of your facilities. Access to your lab will be facilitated by SCC Administration.
- Awardees will be notified if their project is to be funded by the Cancer Frontier Fund (CFF), an initiative of the Foundation for Barnes-Jewish Hospital. These projects will need to be submitted
G. Review Process

SIP is designed to support projects which generate key preliminary data for future NIH grant applications. How well each application addresses the following objectives will factor into the reviewers’ overall impact scores.

The reviewers will be requested to assure the following items are presented:

- Stated aims of a future NIH grant.
- Identification as to why these aims would be judged to have high impact.
- Identification of the key pieces of preliminary data for the success of that future application.
- Presentation of a solid plan for the generation of those data with discussion of how the future NIH grant aims might be modified if results are different than expected.
- If applicable, a multi-PI leadership plan.
- How well the application addresses program objectives will factor into the overall impact score and should be explicitly addressed in comments regarding score-driving strengths and weaknesses.

In addition, applications will be evaluated and scored according to:

- Scientific merit, in accordance with the RFA, and using NIH guidelines for scoring; and
- Potential for achieving high-impact results on an accelerated timeline when compared to the traditional pace of cancer research.

Proposals will be evaluated according to:

- qualifications of the research team
- potential to lead to extramural peer-reviewed research support
- scientific innovation and achievable milestones within the project period
- cancer discovery focus
- translational or clinical care focus
- public health focus
- potential for transformative impact on cancer prevention, diagnosis, treatment and/or outcomes
- all PIs are in good standing with SCC requirements

Although cancer relatedness and scientific merit will be the primary factors in evaluating grant applications for funding, meritorious grants that include the following will likely be viewed more competitively by the committee:

- Collaborative applications from members of more than one program
- Applications that propose to use more than one SCC Shared Resources
- Pre-SPORE or Pre-P01 applications that have been vetted successfully with an NCI program officer
- Proposals should be designed as preliminary studies with results to be used to support a subsequent R01 or SPORE/P01 type grant application

Questions regarding the Siteman Investment Program should be directed to:

Jaclyn McGuire
Senior Grant Specialist, Siteman Cancer Center
Email: mcguirej@wustl.edu
Phone: (314) 454-8439