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 4</td>
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<td>Full applications due by 4:00 pm CST:</td>
<td>April 2</td>
<td>October 1</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
  - SIP has a strong interest in funding translational clinically-focused and device-focused projects, including clinical trials and unfunded correlative studies on otherwise funded clinical trials.
- 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 preliminary data to provide a basis for future NCI/NIH applications (e.g., R01s, R21s, SPOREs, PPGs, etc.)
  - SIP has a strong interest in funding recently well-scored, but unfunded, NIH applications.

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 only submit one (1) Pre-R01 or Multi-PI Pre-R01 application as PI per cycle. 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 Team Science Award(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 Team Science application will not be considered for funding as a Pre-R01 or Multi-PI Pre-R01 in the same cycle.
- All faculty on a SIP application are strongly encouraged to participate in the Pedal the Cause event on September 29-30, 2018. 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 Siteman Kids at 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 cycle 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 cycle dependent upon scientific merit of the projects submitted for review.

There are three types of research mechanisms available:

1a. Pre-R01 Program for Washington University School of Medicine faculty only
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
- Applicants may request up to the full amount and there is no minimum amount required

2. Multi-PI Pre-R01 Program 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. Team Science Program for all WUSTL/SLU cancer researchers

- Encourages new, exploratory and developmental research projects by providing support for project development and may be used for pilot and feasibility studies and device development.
- Program to be used as a precursor for larger, team science-oriented NCI/NIH grants including: SPOREs (P50), PPGs (P01), and U54s
- Total project period may not exceed 2 years
- Combined budget for direct costs for the total project period may not exceed $800,000
- At the time of submission, well-established scientific teams and projects are expected, with an anticipated NCI/NIH submission timeline within 12-24 months of receipt of SIP funds
- In addition to scientific progress, it is expected that there will be significant progress in the administration and organization of the grant throughout the duration of this award. The release of year 2 funds is contingent on the following being accomplished during year 1 of funding: 1) Pre-application consultation meeting with the NCI/NIH; 2) Submission of an External Advisory Board report; and, 3) Presentation on progress with SCC’s Senior Leadership Committee
- PI(s) are strongly encouraged to present all planned projects to SCC’s Senior Leadership Committee prior to submitting to SIP. Senior Leaders will assess readiness for funding and provide feedback to the PI(s). To schedule a presentation with SCC Senior Leaders, contact Nick Fisher at nfisher@wustl.edu.
- 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: 1) Submitted Scientific Report to date, and 2) 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 SCC Shared Resource (Core), unless core services are not relevant to your project. http://www.siteman.wustl.edu/ContentPage.aspx?id=229
- Project must start within six months of receipt of the Notice of Award or funding will be rescinded
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(s); 2) Project title; 3) Abstract; and, 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 best practice to print to PDF versus saving to PDF. The applicant is responsible for previewing the final document in proposalCENTRAL and ensuring no errors occurred in compiling the PDF application.

Required Application Components:
1. Siteman Cancer Center Cover Sheet (Download from website – Updated January 2018)
   - Due to the nature of the sponsor reporting process, SCC requires a description of your research project written in “lay” language. 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/unallowable expenditures below)
   - For Team Science applications, please complete Form Pages 4 and 5 for each project.
     o Team Science applications must budget for biostatistical support where applicable. Support provided by the Siteman Biostatistics Shared Resource (SBSR) for an awarded Team Science project will not be considered as pre-award work for a NCI/NIH grant. Therefore, under SBSR’S pricing model, biostatistical support for an awarded Team Science project will not be subsidized. Effort for biostatistical support should be budgeted in the Team Science application.
5. NIH Biosketches for all key personnel (Instructions and Samples)
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
        Team Science 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 NCI/NIH funding. In this regard, applicants should list potential aims for a NIH proposal. This section is an important criterion for award selection. If the SIP application is in response to a submitted, but unfunded, NCI/NIH application, you have the option to include the Summary Statement as a supporting document in this section (not included in the page limit).
   - If submitting a clinical trial or correlative study, please include an outline of your plan for future development of the hypothesis beyond the initial project described in this application.
   - Team Science applications must include a detailed timeline for submission and meeting Year 2 contingencies outlined above: 1) Pre-application consultation meeting with the NCI/NIH; 2) Submission of an External Advisory Board report; and, 3) Presentation on progress with SCC’s Senior Leadership

10. **SCC Shared Resource/Core Utilization** (1 page maximum)
    - Describe SCC shared resource usage. As noted above, project(s) should utilize at least one SCC shared resource, unless core services are not relevant to the project.
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 from the director(s) for each Siteman Shared Resource you will be using in your research, as well as a letter indicating commitment to provide any compounds/drugs from a pharmaceutical company, if applicable. You may also include other letters of support for the project from appropriate sources (dept chair, div chief, 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
- Graduate student/postdoctoral assistant stipends if relevant to the project with a detailed justification
- Domestic/foreign travel necessary to carry out proposed project based on institutional travel policies
- Computational services
- Other expenses such as lab and core fees, pathology, imaging, etc.
- Consultant costs
- Equipment/technology with the intent to design, test or facilitate a new device and non-office equipment necessary to carry out the proposed project. Requests over $5,000 must include a detailed justification
- Publications costs not to exceed $2,000 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
- Travel not essential to carrying out the proposed research
- Purchasing and binding of periodicals and books
- Dues and membership fees in scientific societies
- Recruiting and relocation expenses
- Administrative or institutional charges for services normally considered overhead (e.g. space rental, utilities, building maintenance)
- Non-medical or personnel services to patients
- Sub-contracts to institutions not affiliated with Siteman Cancer Center
- Pre-award costs
In addition, applic

The objectives will factor into the reviewers’ overall impact scores.

preliminary data for future S

SIP is designed to support projects which involve clinical trials/correlative studies and/or will generate key preliminary data for future NCI/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.
- 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.
- In addition to scientific reviewers, all applications that include a clinical trial will be reviewed by a patient advocate. The patient advocate is asked to review the proposal based on patient-centered issues such as relevance, safety, and feasibility.

**Questions regarding the Siteman Investment Program should be directed to:**

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

The Siteman Investment Program is supported by a variety of sources, including: Pedal the Cause bike challenge and Illumination gala, through the Cancer Frontier Fund at The Foundation for Barnes-Jewish Hospital; The Fashion Footwear Association of New York; the Cancer Center Support Grant from the National Cancer Institute; and the Barnard Trust.

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.
- PRMC, IRB and/or IACUC must be submitted before the award start date, and all awards must have appropriate institutional approvals (e.g. IRB, IACUC, 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. For WU awardees, these projects will need to be submitted through the WU Research Management System (RMS) and be approved by Office of Sponsored Research Services. PDs are to be completed within 2 weeks of notification.

G. Review Process

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.
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