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Siteman Investment Program Research Development Awards Request for Applications (RFA)

A. Deadlines

Biannual announcements:	January 15	July 15
Statement of Intent due by 4:00 pm CST:	March 1	September 1
Full applications due by 4:00 pm CST:	April 1	October 1
Start dates:	July 1	January 1

B. Purpose

- 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
 - Projects directly responsive to addressing breast cancer disparities in North St. Louis County or colorectal cancer disparities in Southern Illinois/Missouri Bootheel region are encouraged and will receive strong consideration
- 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
- Produce preliminary data to provide a basis for future NCI/NIH applications (e.g., R01, R21, SPORE, PPG). SIP has a strong interest in funding recently well-scored, but unfunded, NIH applications

C. Eligibility

- The PI must have a full-time faculty appointment at Washington University (WU), Saint Louis University (SLU), or University of Missouri-Columbia (MU). Faculty from Saint Louis University and University of Missouri-Columbia are required to have a WU Siteman Cancer Center faculty member as co-PI. Effort between co-PIs from different institutions must be comparable and both co-PIs must contribute to the overall project in similar magnitude.
- The contact 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 may submit only one application as contact PI per cycle. A PI is allowed to be a co-investigator, or consultant, on any number of submissions. A faculty member currently funded in the role of contact PI by a SIP RDA is not eligible to submit unless (1) their current award will end by the scheduled start date; or (2) their current award is in a no-cost extension
- Any faculty member may submit an application under the PRE-R01 or CLINICAL TRIAL categories and participate as a project PI/leader on a TEAM SCIENCE application, as long as the projects are scientifically unique. Please note that SIP will not fund the same science multiple times. A project submitted on a TEAM SCIENCE application will not be considered for funding as a PRE-R01 or CLINICAL TRIAL application in the same cycle

- All faculty on a proposal are strongly encouraged to participate in the Pedal the Cause event on September 26-27, 2020. 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
- Siteman Cancer Center priorities (e.g., Catchment Area) are considered in final funding decisions

There are 6 mechanisms within 3 categories (CLINICAL TRIAL, PRE-R01, and TEAM SCIENCE):

CLINICAL TRIAL CATEGORY

1. New Clinical Trial Mechanism

- To support new (not yet active) institutional investigator-initiated, interventional* trials unable to secure external funding
- Clinical trials directly responsive to addressing breast cancer disparities in North St. Louis County are encouraged and will receive strong consideration
 - Clinical trials focused directly on the recruitment of minority populations within the SCC catchment area are encouraged and will receive strong consideration
 - Clinical trials that will be opened at SCC satellite sites and are designed specifically to recruit participants from those locations are encouraged and will receive strong consideration
- Total project period may not exceed 3 years
- Amount requested should reflect what is needed to achieve objectives, not to maximize amount awarded. Combined budget for direct costs for the total project period may not exceed \$300,000

2. Established Clinical Trial Mechanism

- To support ongoing (already active) institutional investigator-initiated, interventional* trials with a proven track of accrual and promising preliminary results, but with insufficient resources to complete the trial
- Total project period may not exceed 2 years
- Amount requested should reflect what is needed to achieve objectives, not to maximize amount awarded. Combined budget for direct costs for the total project period may not exceed \$200,000

The following criteria is applicable to both mechanisms in the CLINICAL TRIAL CATEGORY:

- Allowable budget expenses are limited to clinical research coordination (for recruitment and data collection) and expenses related to the completion of correlative science studies. Faculty salary is unallowable on Clinical Trial Category applications
- Special emphasis will be given during the review process to therapeutic clinical trials and those that are especially responsive to the needs of Siteman's catchment area
- PRMC approval must be obtained prior to SIP RDA grant submission (no exceptions)
- IRB approval must be obtained within 90 days of receipt of the Notice of Award or else risk forfeiture of SIP RDA funding
- SCC expects its support of clinical trials through SIP to supplement support from other sources (WUSTL departments/divisions, pharmaceutical companies, etc). Applicants are expected to outline their other support in the budget form. Applicants without clearly defined other support are unlikely to be funded through SIP. Support from the department and/or division must be detailed in a letter of support.

- *Interventional as defined by the NIH: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes

PRE-R01 CATEGORY

3. Pre-R01 Mechanism

- Used to support a discrete, specified hypothesis driven research project
- To provide 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

4. Pre-R01 Prevention & Control Mechanism

- Used to support a discrete, specified hypothesis driven research project
- To provide support for projects focused on addressing prevention and control, including but not limited to: reducing disparities, health policy, tobacco control, maximizing benefits of cancer genetics research, implementation & dissemination of evidence-based cancer control initiatives
- 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

5. Pre-R01 Mechanism for University of Missouri-Columbia Collaboration

- To support collaborative Pre-R01 projects between Washington University and University of Missouri-Columbia faculty. Effort between co-PIs from both institutions must be comparable and both co-PIs must contribute to the overall project in similar magnitude. Budgets from each institution must be comparable. Projects not meeting these guidelines will not pass administrative review or be scientifically reviewed.
- To provide 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

The following criteria is applicable to all mechanisms in the PRE-R01 CATEGORY:

- Project(s) must be clearly cancer-focused
- Project(s) must have institutional approvals in place and start within 90 days of receipt of the Notice of Award or funding may be rescinded.

TEAM SCIENCE CATEGORY

6. Team Science Mechanism

- 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
- 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 RDA funds. An Internal Advisory Board must already be established and have met at least once prior to Statement of Intent submission. A Letter of Support is required from the IAB Chair summarizing feedback from their latest meeting.

- Total project period may not exceed 2 years
- Combined budget for direct costs for the total project period may not exceed \$800,000
- Project must have institutional approvals in place and start within 90 days of receipt of the Notice of Award or funding may be rescinded.
- 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; 3) Engagement with the Dr. Bettina Drake, Associate Director of Community Outreach and Engagement (COE) and the COE team on minority engagement accruals, and 4) Presentation on progress with SCC's Senior Leadership Committee
- **PI(s) are required to present all planned projects to SCC's Senior Leadership Committee prior to submitting the Statement of Intent.** 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

E. Submission Guidelines

Pre-submission Guidelines for ALL CATEGORIES:

Submission of the Statement of Intent (SOI) form is required and due by 4:00pm CST on the due date listed on Page 1. The SOI form can be accessed via the [SIP RDA website](#) or by [clicking here](#). The SOI is not formally reviewed and approval to submit a full application is automatic; PIs should not expect or anticipate any further correspondence from Siteman Administration following submission of the SOI.

Submission Guidelines for CLINICAL TRIAL CATEGORY:

Combine all documents into one PDF document and submit the application by 4:00pm CST on the deadline, via [proposalCENTRAL](#). The signature page generated by proposalCENTRAL is not required.

Formatting:

- Use Arial 11 pt font for text.
- It is best practice to **print to PDF** versus saving to PDF. The applicant is responsible for reviewing the final document in proposalCENTRAL and ensuring no errors occurred in uploading.

Required Application Components:

1. **Siteman Cancer Center Cover Sheet** ([Download from website](#) – Updated July 2020)
 - Due to the nature of the sponsor reporting process, SCC requires a description of your research project written in “lay” language. 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.
2. **Project Summary/Abstract** (limit to 30 lines)
3. **SIP RDA Clinical Trial Category Budget Form** ([Download from website](#) – Updated July 2020)
 - Amount requested should reflect what is needed to achieve objectives, not to maximize amount awarded.
 - Allowable budget expenses are limited to clinical research coordination (related to recruitment and data collection) and expenses related to the completion of correlative science studies. Faculty salary is unallowable on Clinical Trial Category applications.
 - SCC expects its support of clinical trials through the SIP RDA mechanism to supplement support from other sources (pharmaceutical companies, WUSTL departments/divisions, etc). Applicants are expected to outline their other support in the budget form. Applicants without clearly defined other support are unlikely to be funded through SIP. Support from the department and/or division must be detailed in a letter of support.
4. **NIH Biosketch for Principal Investigator** ([Instructions and Samples](#))

5. **PRMC-Approved protocol and informed consent document(s)**
6. **Statement of Innovation** (1 page maximum)
 - Explain how the clinical trial challenges and seeks to shift current research and/or clinical practice paradigms.
 - Describe any novel approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing.
7. **Recruitment Strategy** (1 page maximum)
 - Describe your planned or current recruitment strategy. Please include the number of potential patients seen at Siteman Cancer Center per year and the number of those patients needed to meet your recruitment goals.
8. **Plans for Future Research** (1 page maximum)
 - Discuss how findings will lead to future research (e.g., subsequent trial, external funding) at the completion of this clinical trial.
9. **Letter(s) of Support**
 - Clinical trials involving drugs must provide proof of drug commitment from the sponsor. Clinical trials needing drug(s) without such documentation will not be considered for funding.
 - A Letter of Support from the applicant's Department Chair (or Division Chief, if applicable) is required. Matching departmental funding must be detailed in this LOS if being provided
 - Applicants may also include other letters of support for the project from appropriate sources (collaborators, mentor, etc.)

Submission Guidelines PRE-R01 and TEAM SCIENCE CATEGORIES:

Combine all documents into one PDF document and submit the application by 4:00pm CST on the deadline, via [proposalCENTRAL](#). The signature page generated by proposalCENTRAL is not required.

Formatting:

- Applicants must use the **NIH PHS 398 forms outlined below, unless otherwise indicated**. Applicants must follow the NIH guidelines when completing the forms included below. NIH forms can be found at: <http://grants.nih.gov/grants/funding/phs398/phs398.html>
- Use Arial 11 pt font for text.
- It is best practice to **print to PDF** versus saving to PDF. The applicant is responsible for reviewing the final document in proposalCENTRAL and ensuring no errors occurred in uploading.

Required Application Components:

1. **Siteman Cancer Center Cover Sheet** ([Download from website](#) – Updated July 2020)
 - 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.
2. **SIP RDA re-submissions only: response to prior SIP RDA critique** (1 page maximum)
 - Resubmissions are encouraged and require a response to prior SIP RDA critiques.
3. **Introduction** (if applicable; 1 page maximum)
 - If this SIP RDA proposal is in response to a submitted, but unfunded, NCI/NIH application, an Introduction is required. The Introduction should summarize substantial additions, deletions, and changes to the application and respond to the issues and criticism in the NIH summary statement. In addition, please include the NIH/NCI Summary Statement as a supporting document in the appendix.
4. **Project Summary and Key Personnel** (PHS 398 Form Page 2)
5. **Budget Pages** (PHS 398 Form Page 4 and 5)
 - A detailed budget justification is required (See allowable/unallowable expenses below)
 - For all applications involving a collaboration with a partner institution (i.e., SLU or MU), please complete Form Pages 4 and 5 for each institution (i.e., Form Page 4 & 5 for WU expenses and Form Page 4 & 5 for SLU/MU expenses). Budgets from each institution must be comparable.

- For Team Science applications, please complete Form Pages 4 and 5 for each project.
 - Team Science applications must budget for biostatistical support where applicable. Support provided by the Siteman Biostatistics Shared Resource (BSR) for an awarded Team Science project will not be considered as pre-award work for a NCI/NIH grant. Therefore, under BSR's pricing model, biostatistical support for an awarded Team Science project will not be subsidized. 10% effort for BSR support is expected for all pre-SPORE applications.
- 6. **NIH Biosketches for all key personnel** ([Instructions and Samples](#))
- 7. **Specific Aims and Research Strategy**
 - **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.
 - **Research Strategy**
 - Pre-R01 Category page limit: 6 pages maximum
Team Science Category 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.
 - I. 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.
 - II. 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.
 - III. 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.
- 8. **Bibliography and References Cited**
- 9. **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.

10. **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.
 - 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
11. **SCC Shared Resource/Core Utilization** (1 page maximum)
 - Describe SCC shared resource usage. 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>
12. **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 allocated and no aspect of the project can begin (including non-human subject research components) without documentation of required approvals.
13. **Letter(s) of Support**
 - Team Science applications are required to include a LOS from their IAB Chair summarizing their most recent IAB meeting feedback.
 - Applicants must 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).

Note: Appendix materials are not allowed unless specifically requested above.

Budget Guidelines for PRE-R01 and TEAM SCIENCE CATEGORIES:

Expenditures Allowed:

- Salary support for investigators and other relevant faculty collaborators or staff. The current NIH salary cap must be used where applicable
- Research supplies
- Per diem charges for patients if part of a clinical study, not reimbursable by standard payment terms
- Technical assistance
- Graduate student/postdoctoral 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



Additional Guidelines for ALL CATEGORIES/MECHANISMS

Applications must include all sections. Late and/or incomplete applications will not be accepted. Please submit your application at least 48 hours in advance of the deadline if you would like an administrative review prior to the deadline.

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.

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.
- For CLINICAL TRIAL CATEGORY, PRMC approval must already be obtained at time of grant submission and IRB approval must be obtained within 90 days of receipt of the Notice of Award. For PRE-R01 and TEAM SCIENCE CATEGORIES, all awards must have appropriate institutional approvals (e.g. PRMC, IRB, IACUC, etc.) within 90 days of receipt of the Notice of Award and before funds will be allocated. No aspect of the project can begin (including non-human subject research components) without documentation of all required approvals.
- Projects must start within 90 days of receipt of the Notice of Award or funding may be rescinded.
- 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.

G. Review Process

The SIP RDA 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.

Applications will be evaluated and scored according to:

- Scientific merit, in accordance with the RFA, and using NIH guidelines for scoring
- Potential for achieving high-impact results on an accelerated timeline when compared to the traditional pace of cancer research
- CLINICAL TRIAL applications will be evaluated and scored primarily on the potential overall scientific impact of the trial, as well as on the potential clinical benefit to patients
- In addition to internal and external scientific faculty reviewers, all CLINICAL TRIAL applications 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

H. Questions

For any questions, please contact:
Jaclyn McGuire, MPH
Research Administrator, Alvin J. Siteman Cancer Center
Email: mcguirej@wustl.edu

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