

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

A. Deadlines

RFA release date:	January 19, 2024
Statement of Intent due by 4:00 pm CST:	March 15, 2024
Full applications due by 4:00 pm CST:	April 11, 2024
Start dates:	July 1, 2024

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.
- Produce preliminary data to provide a basis for future NCI/NIH application (e.g., R01, R21, SPORE, PPG). SIP RDA has a strong interest in funding recently well scored, but unfunded, NIH applications.
- Projects directly responsive to addressing health disparities in SCC's catchment area are encouraged and will receive strong consideration. Examples include projects addressing breast cancer disparities in North St. Louis County or colorectal cancer disparities in the Southern Illinois/Missouri Bootheel region.
 - The full list of catchment area priorities based on community feedback and cancer burden includes the following: breast, prostate, lung and smoking, colorectal, HPV, hematologic malignancies, and obesity. For details on the cancer burden and social determinants of health for the catchment area, please [examine the Community Dashboard](#), part of the [Siteman Cancer Center DASHboards \(Data and Statistics Hub\)](#).
 - For additional guidance on the needs and priorities of the catchment, please reach out to Dr. Bettina Drake at drakeb@wustl.edu.
- 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.
 - For more information about research collaborations with community partners within the catchment area, please contact Katie Hoey, Program Manager of External Partnerships at hoey@wustl.edu.
- Catalyze discoveries by building bridges among disciplines and researchers.
- **Assumptions:** All projects should further SCC's research and scientific mission through responsible stewardship of philanthropic funds. 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.

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 SLU and MU 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.
- **NEW:** The contact PI submitting the application must either a) be an approved Siteman Cancer Center member by the Statement of Intent deadline or b) have submitted an acceptable Siteman Cancer Center membership application by the SIP RDA full application deadline. Questions regarding membership should be directed to sitemanmembership@wustl.edu.
- **NEW: The contact PI AND Co-PI(s) (if applicable) must each have a minimum of 5% effort dedicated to the project.** Any proposed effort lower than 5% should be discussed with SCC administration prior to application submission. Salary does not have to be included in the budget (i.e. may be cost-shared), but the PI and co-PI(s) must have protected time available to dedicate to the SIP RDA project.
- If the contact PI is submitting to the Phase 0/1 Brain Tumor Center (BTC) Clinical Trial mechanism, they must be a member of the SCC Brain Tumor Center. Non-members who are interested in this opportunity should contact Amie Booth, amie.booth@bjc.org.
- A faculty member may submit only one application as contact PI per cycle unless their prospective project is a MU/WU pre-R01 or a Phase 0/1 BTC Clinical Trial AND the other project proposed is for separate science. 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 RDA 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 required to participate in the Pedal the Cause (PTC) event in September 2024. PTC participation (fundraising, riding, and/or volunteering) is mandatory for all SIP RDA awardees in years of active funding, as outlined in the Notice of Award. PTC is one of the largest donors to SIP RDA 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 PTC, including as a rider, virtual rider, or volunteer. Please visit <http://pedalthecause.org> for more information.
- All faculty on a proposal are also strongly encouraged to engage with the Foundation for Barnes-Jewish Hospital in fundraising activities such as speaking engagements, interviews or video recordings related to your research, small group gatherings, and other events.
- If a faculty member has received SIP funding previously, they must clearly demonstrate that the science of the proposed project is new and distinct from the previously funded project(s).

D. Terms of the Award

- Acceptance of funds implies a firm commitment to provide a progress report for each project year by the deadline outlined in the NOA, a meeting with SCC team upon project close, and subsequently, an annual update for a three-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, 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 or BTC Administration, depending upon the award mechanism.

- 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 the Office of Sponsored Research Services (OSRS).
- For CLINICAL TRIAL CATEGORIES, protocols must have been submitted to the PRMC by the SIP full application deadline.
- No funding will be released prior to receipt of appropriate institutional compliance approvals (e.g. PRMS, IRB, IACUC, etc.). Projects without necessary regulatory approvals in place 180 days following receipt of the Notice of Award will be reviewed by SCC leadership, which may result in a change of award terms or forfeiture of SIP RDA funding. No aspect of the project can begin (including non-human subject research components) without documentation of all required approvals.
- Awardees may request adjustments to their SCC role/responsibilities, percent effort, or award period for personal or family situations including, but not limited to, parental leave, child care, elder care, medical conditions, or a disability.

E. 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 adapted NIH guidelines for scoring. Please note that the SIP RDA review is run similar to an NIH study section and while its score drivers are similar, there is an important distinction: the SIP RDA exists to support projects that need vital data to become competitive for an R01 or similar award. For this reason, an IMPORTANT score driver in the SIP RDA review is the potential for future funding. It is the PI's job to lay out how the SIP RDA funds will ensure a competitive future application. One page is dedicated to this purpose and that page is carefully evaluated during the Study Section meeting and by Siteman Senior Leadership when making funding decisions.
- Potential for achieving high-impact results on an accelerated timeline when compared to the traditional pace of cancer research.
- COE SUPPLEMENT CATEGORY proposals will be reviewed separate of the SIP RDA Study Section by faculty and community experts.
- **NEW:** CLINICAL TRIAL CATEGORY applications will be evaluated and scored according to the following priorities:
 - Research team with a history of strong performance
 - Sizeable accrual with clear justification that enrollment targets can be met in a reasonable timeframe.
 - Ability to meet the specific needs of patients in our catchment, especially underserved individuals from racial and ethnic minorities and/or from rural and medically underserved areas
 - Innovative/cutting edge nature of science
 - True need for trial within SCC portfolio or projects.
 - Priority will be given to trials that can be opened at multiple SCC satellite sites, ensuring accessibility to a broad spectrum of patients
- In addition to a subcommittee of clinician faculty reviewers, all CLINICAL TRIAL CATEGORY and Prevention and Control interventional 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.

F. Application Guidelines and Details by Mechanism

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.

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 before the deadline if you would like an administrative review prior to the deadline.

There are SEVEN mechanisms within FOUR categories:

CLINICAL TRIAL

PRE-R01

TEAM SCIENCE

COE SUPPLEMENT

You may **click on the title of any category above** to navigate to the specific sections within this RFA. You may also scroll down and review all category guidelines.

For any questions, please contact:

Steve Baer

Program Manager, Alvin J. Siteman Cancer Center

Email: Steve.Baer@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 Cancer Center Support Grant from the National Cancer Institute; the Director's Discovery Fund; the Alvin J. Siteman Fund; and the Barnard Trust.

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.
- The [SCC Patient Research Advisory Board](#) (PRAB) is designed to help investigators by having community members review proposals and give feedback. Awardees are required to meet with PRAB within 6 months of receipt of the Notice of Award to discuss and obtain feedback related to the study. Please note that the trial can be activated prior to meeting with PRAB.
- To ensure diverse accrual to clinical trials, distribution of funds may be based on meeting accrual milestones and, specifically, accrual of minorities. Exact accrual time points and released funds will be formalized and agreed upon at the time of the award.
- Total project period may not exceed 3 years.
- Amount requested should reflect what is needed to achieve objectives, not to maximize amount awarded. The total requested amount for direct costs for the entire project period may not exceed \$300,000.
- Allowable budget expenses are limited to clinical research coordination (for recruitment and data collection) and expenses related to the completion of correlative science studies.
- **NEW:** See new list of priorities by which trials will be evaluated on page 3.

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.
- **NEW:** Amount requested should reflect what is needed to achieve objectives, not to maximize amount awarded. **The total requested amount for direct costs for the entire project period may not exceed \$100,000.**
- Allowable budget expenses are limited to clinical research coordination (for recruitment and data collection) and expenses related to the completion of correlative science studies.
- **NEW:** See new list of priorities by which trials will be evaluated on page 3.

3. Phase 0/1 Brain Tumor Center (BTC) Clinical Trial

- To support either new (not yet active) or ongoing (already active) institutional investigator-initiated, interventional* trials unable to secure external funding. This mechanism will provide pilot funding to develop innovative early-phase clinical trials to accelerate the development of novel drug therapies for brain tumors.
 - For the Phase 0/1 Brain Tumor Center (BTC) Clinical Trial mechanism only, a trial may be submitted that is NOT interventional, provided there is a clear path and plan in place to expand to an interventional study in the future.
- The objective of the phase 0 component of a clinical trial may include the following: obtaining pharmacokinetic data and the brain-to-plasma ratio, evaluating modulation of a presumed drug target, optimizing target assay methodology using either molecular or radiological techniques, or assessing the pharmacokinetic and pharmacodynamic relationship.
- The proposed study must include a phase 0, window-of-opportunity, or phase 1 component with plans to examine human tissue after drug administration. The tissue may include tumor, blood, cerebrospinal fluid, or other tissue types.
- Clinical trials directly responsive to addressing brain tumor in the St. Louis region 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.
- **NEW:** Amount requested should reflect what is needed to achieve objectives, not to maximize amount awarded. **The total requested amount for direct costs for the entire project period may not exceed \$150,000.**

The following criteria applies to all mechanisms in the CLINICAL TRIAL CATEGORY:

- Contact PI must be an active clinician.
- Protocol must be submitted to the PRMC by the SIP full application deadline.
- No funding will be released prior to receipt of PRMC and IRB approvals. Projects without necessary regulatory approvals in place 180 days following receipt of the Notice of Award will be reviewed by SCC leadership, which may result in a change of award terms or forfeiture of SIP RDA funding. No aspect of the project can begin (including non-human subject research components) without documentation of all required approvals.
 - **NEW:** To avoid delays in project start-up, **please submit to PRMC as early as you are able.** It is recommended that you consult with the protocol development office early in the process. If your clinical trial involves an investigational drug or device, you may also need to undergo FDA review. You will not be able to submit for IRB approval until PRMC (and FDA, if required) approval is obtained.
- 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.
- **Other Support Expectation:** SCC expects its support of clinical trials through SIP RDA 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 RDA.** 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.*

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 to **print to PDF** each document 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 2023)
 - 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. As an example, the lay public in general does not know what a kinase is. They do know that proteins must modify or change other proteins. Please steer clear of scientific words in your lay abstract.
 - The Becker Library offers a variety of services and resources to assist applicants with making written materials easier to understand. For more information, visit the Becker

Health Literacy and Communication webpage at:

<https://becker.wustl.edu/services/health-literacy-communication/>

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 RDA. Support from the department and/or division must be detailed in a letter of support.
 - **Facilities and Administrative (F&A)/Indirect Costs:** Do not include indirect costs at time of submission. Based on the funding source, indirect costs may be added post-award.
4. **NIH Biosketch for Principal Investigator** ([Instructions and Samples](#))
5. **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**
 - 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.
 - 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.
 - Applicants may also include other letters of support for the project from relevant sources, particularly from all funding sources.
 - Applicants submitting to the Phase 0/1 Brain Tumor Center Clinical Trial mechanism must include a LOS from BTC Tumor Bank leadership to confirm the feasibility of tissue collection.

1. Pre-R01 Mechanism: *Made possible by Pedal the Cause*

- 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; prevention and control studies, etc.
 - **Prevention and Control Focused Projects:** The intent is to support projects focused on addressing prevention and control, including but not limited to: reducing disparities, health policy, tobacco control, maximizing benefits of cancer genetics research, and implementation and dissemination of evidence-based cancer control initiatives.
- Total project period may not exceed 2 years.
- The total requested amount for direct costs for the entire project period may not exceed \$200,000.
- Applicants may request up to the full amount and there is no minimum amount required.

2. 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.
- The total requested amount for direct costs for the entire 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
- No funding will be released prior to receipt of necessary compliance approvals. Projects without necessary regulatory approvals in place 180 days following receipt of the Notice of Award will be reviewed by SCC leadership, which may result in a change of award terms or forfeiture of SIP RDA funding. No aspect of the project can begin (including non-human subject research components) without documentation of all required approvals.

Submission Guidelines for PRE-R01 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:

- 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 to **print to PDF** each document 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 2023)**

- 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. As an example, the lay public in general does not know what a kinase

is. They do know that proteins must modify or change other proteins. Please steer clear of scientific words in your lay abstract.

- The Becker Library offers a variety of services and resources to assist applicants with making written materials easier to understand. For more information, visit the Becker Health Literacy and Communication webpage at:
<https://becker.wustl.edu/services/health-literacy-communication/>
- 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)
 - Applications involving a collaboration with a partner institution (i.e. SLU, MU) must complete Form Pages 4 and 5 for each institution (i.e. Form Page 4 and 5 for WU expenses and Form Page 4 and 5 for SLU/MU expenses). Budgets from each institution must be comparable.
 - **Facilities and Administrative (F&A)/Indirect Costs:** Do not include indirect costs at time of submission. Based on the funding source, indirect costs may be added post-award.
- 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
 - 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. Biostatistical Plan (2 pages maximum)**

- A formal statistical plan must be included with the proposal. Applicants can reach out to the Siteman Biostatistics and Qualitative Shared Resource (BQSR) at the following link for grant writing resources: <https://publichealthsciences.wustl.edu/research/biostatistics-shared-resource/grant-writing-resources/>
- **NEW:** Applicants should work with a statistician to provide the statistical plan. The detailed statistical considerations should be clearly described in this section.
- **NEW:** Appropriate statistical considerations may include, but are not restricted to:
 - Specification of the study design and the endpoints.
 - Justification of sample size, including power calculations needed to achieve significant differences between the study groups. If a formal power calculation is used, the authors should describe the primary outcome on which the calculation is based, all the quantities used in the calculation (such as effect size, alpha level and power) and the resulting target sample size per study group.
 - A proper analysis plan for data collected, including rationale for the selection of specific statistical tests.
 - Identification of the responsible party that will be overseeing the implementation of the statistical plan throughout the project to ensure appropriate statistical support and collaborations in place.
 - Description of the blinding procedures for the personnel doing assessments. If some observations are impossible to blind – i.e., a drug that has an obvious phenotypic impact on the treated animals – the implications should be described.

10. 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.

11. 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.

12. 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. If no shared resources are utilized for the project, please include a page stating not applicable. <https://siteman.wustl.edu/research/shared-resources-cores/>

13. Compliance Document(s)

- Include a page indicating the status of all applicable compliance 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. If no compliance is needed, please include a page stating not applicable.

14. **Letter(s) of Support**

- 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 (department chair, division chief, collaborators, mentor, etc).

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

Budget Guidelines**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
- 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
- EAB/IAB honorarium and meeting expenses
- Budgeting for the purchase of equipment is unallowable on SIP grants without prior approval from SCC administration. Non-office equipment and/or technology with the intent to design, test, or facilitate a new device must be required for completion of the project and must not be reasonably accessible elsewhere on campus. All requests must include a detailed justification.

Team Science Mechanism

- 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 **three or more 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.
- The total requested amount for direct costs for the entire project period may not exceed \$800,000.
- No funding will be released prior to receipt of necessary compliance approvals. Projects without necessary regulatory approvals in place 180 days following receipt of the Notice of Award will be reviewed by SCC leadership, which may result in a change of award terms or forfeiture of SIP RDA funding. No aspect of the project can begin (including non-human subject research components) without documentation of all required approvals.
- 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 will be contingent on the following being accomplished during year 1 of funding:
 - Pre-application consultation meeting with the NCI/NIH;
 - Submission of an External Advisory Board report;
 - Engagement with Dr. Bettina Drake, Associate Director of Community Outreach and Engagement (COE) and the COE team on minority engagement accruals;
 - 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 Leadership, 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. The total requested amount for direct costs for the 1 year may not exceed \$400,000. The following documents are required with submission:
 - Submitted Scientific Report to date
 - Internal and External Advisory Board Reports

Submission Guidelines TEAM SCIENCE 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:

- 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 to **print to PDF** each document 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 2023)
 - 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. As an example, the lay public in general does not know what a kinase is. They do know that proteins must modify or change other proteins. Please steer clear of scientific words in your lay abstract.

- The Becker Library offers a variety of services and resources to assist applicants with making written materials easier to understand. For more information, visit the Becker Health Literacy and Communication webpage at: <https://becker.wustl.edu/services/health-literacy-communication/>
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)
 - Applications involving a collaboration with a partner institution (i.e. SLU, MU) must complete Form Pages 4 and 5 for each institution (i.e. Form Page 4 and 5 for WU expenses and Form Page 4 and 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 and Qualitative Research Shared Resource (BQSR) for an awarded Team Science project will not be considered as pre-award work for a NCI/NIH grant. Therefore, under BQSR's pricing model, biostatistical support for an awarded Team Science project will not be subsidized. 10% effort for BQSR support is expected for all pre-SPORE applications.
 - **Facilities and Administrative (F&A)/Indirect Costs:** Do not include indirect costs at time of submission. Based on the funding source, indirect costs may be added post-award.
 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**
 - 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.
- IV. **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.
 - V. **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.

VI. 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:
 - Pre-application consultation meeting with the NCI/NIH;
 - Submission of an External Advisory Board report; and
 - 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. If no shared resources are utilized for the project, please include a page stating not applicable. <https://siteman.wustl.edu/research/shared-resources-cores/>

12. Compliance Document(s)

- Include a page indicating the status of all applicable compliance 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. If no compliance is needed, please include a page stating not applicable.

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 (department chair, division chief, collaborators, mentor, etc).

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

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
- 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
- EAB/IAB honorarium and meeting expenses
- Budgeting for the purchase of equipment is unallowable on SIP grants without prior approval from SCC administration. Non-office equipment and/or technology with the intent to design, test, or facilitate a new device must be required for completion of the project and must not be reasonably accessible elsewhere on campus. All requests must include a detailed justification.

Community Outreach and Engagement (COE) Supplement Mechanism**Purpose:**

- To provide supplemental funding to support collaborative investigative teams or individual scientists who propose innovative research projects, which, if successful, would have a major impact in developing, implementing, or disseminating innovative and effective interventions to prevent, reduce, or eliminate cancer disparities and advance health equity across the catchment.
- To support research addressing community-prioritized research questions, cross-cutting issues such as social determinants of health across sectors, multiple levels and systems that contribute to cancer disparities.
- Examples of cancer disparities or community-engaged research topics are available upon request (contact Sarah Van Vickie-Chavez, sarahv@wustl.edu), including cancer disparities in basic science research.

Eligibility and Details:

- The COE SUPPLEMENT funding opportunity may supplement any current grant/funding award, including but not limited to SIP RDAs, NCI/NIH grants, private foundation awards, and other institutional pilot awards. Multi-project awards (e.g., SPORes, Team Science SIP RDAs) may request supplemental funding for each project funded by the overall parent award.
- The applicant must have a full-time faculty appointment at Washington University, be a SCC member at the time of submission (or have submitted an application for SCC membership by the SIP RDA full application deadline), and serve in the role as PI on the parent award associated with the supplemental application.
- Total project period may not exceed 1 year.
- The total requested amount for direct costs for the entire project period may not exceed \$50,000. Applicants may request up to \$100,000 directs with pre-approval from the Associate Director of COE, Dr. Bettina Drake (drakeb@wustl.edu).
- Total number of supplemental awards are dependent upon available funding and scientific value. SCC priorities are considered in final funding decisions.

Submission Guidelines COE SUPPLEMENT 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:

- 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 to **print to PDF** each document 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 2023)
 - 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. Please steer clear of scientific words in your lay abstract.
 - The Becker Library offers a variety of services and resources to assist applicants with making written materials easier to understand. For more information, visit the Becker Health Literacy and Communication webpage at: <https://becker.wustl.edu/services/health-literacy-communication/>
2. **Budget Pages** (PHS 398 Form Page 4 and 5)
 - A detailed budget justification is required (See allowable/unallowable expenses below). The following are allowable expenses for this category which deviate from the lists below: travel

and/or registration costs to attend conferences for academic and community investigators if there are relevant (e.g., health equity, disparities focused) agenda topics

- **Facilities and Administrative (F&A)/Indirect Costs:** Do not include indirect costs at time of submission. Based on the funding source, indirect costs may be added post-award.
3. **NIH Biosketches for All Key Personnel** ([Instructions and Samples](#))
 4. **Specific Aims and Research Strategy**
 - **Specific Aims** (1 page maximum)
 - State concisely the goals of the proposed research and summarize the expected outcome(s). List succinctly the specific objectives of the research proposed.
 - **Research Strategy**
 - COE SUPPLEMENT page limit: 6 pages maximum
 - Start each section with the appropriate section heading – Significance, Innovation, Approach, Impact on Cancer Disparities, and Integration of Community Priorities. 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, clinical practice, or community- based research 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.
 - IV. **Impact on Cancer Disparities**
 - Describe how the research project, if successful, will have a major impact on the prevention, reduction, and elimination of cancer disparities and promoting health equity across the SCC catchment.
 - V. **Integration of Community Priorities**
 - i. Discuss how proposal addresses community-prioritized research questions, including cross-cutting issues such as social determinants of health across sectors, multiple levels and systems that contribute to cancer disparities.
 - ii. Outline community engagement strategies and/or plans to involve patient advocates
 5. **Bibliography and References Cited**
 6. **Recruitment Strategy** (if applicable) (1 page maximum)

- Describe your planned or current recruitment strategy or minority and/or rural patients. 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.
- 7. **Future Plans** (1 page maximum)
 - Discuss how the findings from your project will be used to write a proposal for subsequent funding. Outline how this project will inform and lead to the next study.
- 8. **Compliance Document(s)**
 - Include a page indicating the status of all applicable compliance approvals as listed on the cover sheet (e.g., 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. If no compliance is needed, please include a page stating not applicable.
- 9. **Letter(s) of Support**
 - COE Supplement applications are encouraged to include a LOS from community partners.
 - If COE funding will supplement support from other sources (e.g. other WUSTL departments/divisions, etc.), support from the department and/or division must be detailed in a letter of support.
- 10. **Parent Grant**
 - COE Supplements are designed to expand the impact and enhance funded research projects through disparities-focused sub-aims. Provide active* “parent” grant details including grant number, funding agency, project period, abstract, and research narrative.
 - * If the parent grant is a SIP award, a COE supplement may be submitted up to six months after expiration date.

Budget Guidelines

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
- 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 and
- 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 and Pre-award costs
- EAB/IAB honorarium and meeting expenses
- Budgeting for the purchase of equipment is unallowable on SIP grants without prior approval from SCC administration. Non-office equipment and/or technology with the intent to design, test, or

facilitate a new device must be required for completion of the project and must not be reasonably accessible elsewhere on campus. All requests must include a detailed justification.