CLINICAL TRIAL

SITEMAN CANCER CENTER | WashU Medicine | BJC HealthCare

Siteman Investment Program
Research Development Awards

Program Overview

The Siteman Investment Program (SIP) provides funding to support innovative, high-impact cancer research across the continuum of discovery, diagnosis, treatment, and prevention. This program is designed to advance promising ideas with strong potential for future external funding and meaningful clinical or community impact.

Purpose and Scope of SIP RDA

- 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
- SIP RDA has a strong interest in funding recently well scored, but unfunded, NIH applications.
    - SIP RDA is meant to fund projects that have excellent potential for NIH/NCI funding (e.g., R01, SPORE, PPG) but need additional data
- Projects directly responsive to addressing health disparities in SCC's catchment area are encouraged and will receive strong consideration

Available Funding Categories

Category	Primary Focus	Funding
Clinical Trial	New institutional investigator-initiated, interventional trials unable to secure external funding	Up to $300,000 over 3 years
See individual RFAs for other SIP RDA categories below on the SIP RDA website.		
Team Science	Multi-project collaborative programs preparing for NIH/NCI submissions within 12–24 months (P50, P01, U54).	Up to $800,000 over 2 years
Pre-R01 – General	Pilot, secondary analysis, technology development, and other hypothesis-driven research projects with preliminary data.	Up to $200,000 over 2 years
Pre-R01 – Prevention and Control	Research addressing cancer prevention, survivorship, implementation science, policy, genetics, and cancer control in the catchment area.	Up to $200,000 over 2 years
Pre-R01 – University of Missouri Collaboration	Collaborative Pre-R01 projects between WashU and University of Missouri faculty.	Up to $200,000 over 2 years
Pre-R01 – Head and Neck	Translational or clinical research focused on head and neck cancers.	Up to $200,000 over 2 years
Genome Integrity Development Award (GIDA)	Pilot projects in genome integrity conducted with Center for Genome Integrity (CGI) collaborators.	Up to $100,000 over 2 years
Partner Prevention & Control Interventional Clinical Trial	Prevention and control intervention trials conducted with at least one SCC catchment-area health system partner.	Up to $100,000 over 2 years
COE Supplement	Community-engaged research addressing cancer burden in the SCC catchment area.	Up to $50,000 over 1 year
Martin Glioblastoma Research Fund Awards	Glioblastoma research across disciplines.	Up to $50,000 over 1 year

SIP RDA is supported by a variety of sources including: The Cancer Frontier Fund at The Foundation for Barnes-Jewish Hospital, which includes gifts from Pedal the Cause's annual bike challenge, The Foundation's annual Illumination Gala, and donations throughout the year; the Alvin J. Siteman Cancer Research Fund; Swim Across America – St. Louis; and various philanthropic gifts via Siteman Cancer Center.

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Siteman Investment Program
Clinical Trial Category
2026 Cycle 2 Request for Applications (RFA)

A. Category Overview

Available funding: Up to $300,000 over 3 years

Timeline:

Date of Announcement	**July 23, 2026**
REQUIRED Statement of Intent due by 4:00 PM CST	**August 20, 2026**
Full Applications due by 4:00 pm CST	**September 24, 2026**
Project Start Date	**January 2027**

B. Purpose of Clinical Trial Category and Expectations

- To support new (defined as not yet active or active with zero accruals) institutional investigator-initiated, interventional* trials unable to secure external funding.
    - Clinical trials directly responsive to addressing the following needs will be given strong consideration:
        - Breast cancer disparities in North St. Louis County
        - The recruitment of minority populations within the SCC catchment area
        - Accessibility and ability to complete study activities at SCC satellite sites
    - * *"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.*
- To ensure clinical trials reflect SCC's patient population, distribution of funds may be based on meeting specific accrual milestones. Exact accrual time points and released funds will be formalized and agreed upon at the time of the award.
- **Protocol must be submitted to the PRMC by the SIP full application deadline.**
- 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.
- **Budget Details:** 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. See additional details on page 3.
- **Other Support Expectation:** SCC expects its support of clinical trials through SIP RDA to be supplemented by support from other sources (WUSTL departments/divisions, pharmaceutical companies, etc.).
    - **NEW:** Other sources of support are no longer required to be detailed in the application. However, it is required that awardees will have secured and will submit documentation of other sources of support by the start date of the award. Applicants who have already secured other sources of support are encouraged to submit this information at the time of application. Failure to secure sufficient supplemental funding may result in loss of award.
- **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. Additional Guidance and Resources

- Ideal projects will catalyze discoveries by building bridges among disciplines and researchers.
- Projects directly responsive to addressing health disparities in SCC's catchment area are encouraged and will receive strong consideration.
    - The full list of catchment area priorities based on community feedback and cancer burden includes the following: breast, prostate, lung, colorectal, tobacco cessation, HPV, and cancer survivorship.
    - For details on the cancer burden and social determinants of health for the catchment area, please consult 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, Associate Director of Community Outreach & Engagement, at drakeb@wustl.edu.
- PIs are highly encouraged to meet with the SCC Patient Research Advisory Board (PRAB), or an equivalent group, prior to, or within 2 months of receipt of funding to discuss and obtain feedback related to the study.

D. Eligibility

- **Faculty Appointment**: The PI must have a full-time faculty appointment at the Assistant Professor, Associate Professor, or Professor level* WashU (WU).
    - ***NEW:** Faculty members at the Instructor level are no longer eligible to submit to SIP RDA. Instructors are encouraged to pursue funding from the ACS IRG (American Cancer Society Institutional Research Grant) and the Siteman Travel Awards.
- **Contact PI Must be an Active Clinician*.**
    ** An active clinician must be PI of any therapeutic/treatment protocol, but this is NOT required for interventional trials that do not involve research drugs/treatments.*
- **Siteman Membership**: The contact PI submitting the application must either a) be an approved Siteman Cancer Center member or b) have submitted an acceptable Siteman Cancer Center membership application by the application deadline.
    - Questions regarding membership should be directed to sitemanmembership@wustl.edu.
- **SCC Research Program**: The contact PI may be a member of ANY research program at Siteman Cancer Center
- **5% Minimum Effort**: 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
- **Info for Current SIP RDA Awardees**: A faculty member currently funded in the role of contact PI by a SIP RDA is not eligible to submit an application as contact PI unless (1) their current award will end by the scheduled start date or (2) their current award is in a no-cost extension.
- **Multiple SIP Submissions per Cycle**: A faculty member may submit only one application as contact PI per cycle unless their prospective project is a MU/WU Pre-R01 project or a submission to the Clinical Trial mechanism AND the science is distinct. A PI is allowed to be a co-investigator, or consultant, on any number of submissions.

  - Any faculty member may submit an application under the Pre-R01 or Clinical Trial categories and participate as a co-PI/project PI/leader on a Team Science application, as long as the projects are scientifically unique. 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.
- **Distinct Science**: Please note that SIP RDA will not fund the same science multiple times. If a faculty member has received SIP funding previously (or any other internal funding from Siteman Cancer Center such as a Catalyst Award), they must clearly demonstrate that the science of the proposed project is new and distinct from the previously funded project(s).

E. Terms of the Award

- Full terms will be detailed in the notice of award. The following are general expectations.
  - 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 awardees will be expected to adhere to progress reporting requirements.
  - 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.** This 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:** If the applicant had a pending NIH application at the time of SIP RDA submission that results in funding AND is determined to be overlapping science, 100% of the SIP RDA award must be returned.
  - 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.
  - All PIs and co-PIs on a proposal are required to participate in Pedal the Cause (PTC) in the form of fundraising, riding, and/or volunteering. PTC is one of the largest donors to SIP RDA and their organization exists solely to fund cancer research grant applications at Siteman Cancer Center and Siteman Kids at St. Louis Children's Hospital. Please visit http://pedalthecause.org for more information.
  - PIs and co-PIs 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.

F. Budget

Expenditures Allowed:

- Allowable budget expenses are limited to clinical research coordination (for recruitment and data collection) and expenses related to the completion of correlative science studies.

Expenditures NOT Allowed:

- Faculty salary
- Sub-contracts to institutions not affiliated with Siteman Cancer Center and pre-award costs
- All other expenditures not detailed above.

G. Application Guidelines

- 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.
    - **NEW REQUIREMENT FOR CLINICAL TRIALS:** For clinical trial submissions, a formal letter of support from the Siteman Protocol Development (PD) office is required to accompany the statement of intent submission. Please reach out to protocoldevelopment@wustl.edu with any questions.
- Use Arial 11 point font for text.
- Use the NIH PHS 398 forms, 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.
- Applications must include all appropriate components (see section H below).
- Combine all documents into one PDF document and submit the application via proposalCENTRAL. The signature page generated by proposalCENTRAL is not required. It is best to **print to PDF** each document versus saving to PDF.
- Late and/or incomplete applications will not be accepted.
- **NEW GUIDANCE:** Please ensure that your proposal is written in such a way that it is easily understood by scientists outside of your specific field to maximize understanding and enable reviewers to provide helpful feedback. The SIP RDA review committee is made up of a pool of reviewers within the SCC community with a wide range of scientific expertise.

H. Application Components

1. **Siteman Cancer Center Cover Sheet (Updated July 2026)**
    - SCC requires a description of your research project written in plain language. The purpose of the plain 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 general public 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 plain language 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.
    - **NEW:** It is very important that applicants detail how they have responded to prior critiques. Reviewers will have access to previous critiques and the applicant's response.
3. **NEW: 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/Abstract** (limit to 30 lines)
5. **SIP RDA Clinical Trial Category Budget Form (Updated February 2025)**
    - Amount requested should reflect what is needed to achieve objectives, not to maximize amount awarded.
    - **NEW:** SCC expects its support of clinical trials through the SIP RDA mechanism to be supplemented by support from other sources (pharmaceutical companies, WUSTL departments/divisions, etc). Applicants who have already secured other sources of support

are encouraged to submit this information at the time of application, but it is no longer required.
    - **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 Biosketch for Principal Investigator**
    - **NEW:** Applicants may submit the new SciENcv Common Form OR the previous NIH Biosketch format to satisfy this requirement.
7. **Protocol and Informed Consent Document(s)**
8. **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.
9. **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.
10. **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.
11. **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.
    - **NEW:** Applicants may include other letters of support for the project from relevant sources, particularly from all funding sources. A Letter of Support from the applicant's Department Chair (or Division Chief, if applicable) is no longer required at the time of submission, but it is required that awardees will have secured and will submit documentation of other sources of support by the start date of the award.

Note: Appendix materials are <u>not allowed</u> unless specifically requested above.

I. Review Process

- **CLINICAL TRIAL** proposals will be reviewed separate from the SIP RDA Study Section by a subcommittee of active clinicians and a patient advocate 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 all patients in our catchment, especially underserved individuals including those who are un/underinsured and/or from rural and medically underserved areas.
    - 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
    - The patient advocate is asked to review proposals based on patient-centered issues such as relevance, safety, and feasibility.

For any questions, please contact:
Steve Baer, Program Manager
Email: Steve.Baer@wustl.edu