PROGRAM GUIDELINES AND APPLICATION INSTRUCTIONS
SU2C COLORECTAL CANCER HEALTH EQUITY DREAM TEAM GRANT PROGRAM

ABOUT STAND UP TO CANCER

Stand Up To Cancer® (SU2C) raises funds to accelerate the pace of research to get new therapies to patients quickly and save lives now. SU2C was established in 2008 by media and entertainment leaders who utilize these communities' resources to engage the public in supporting a new, collaborative model of cancer research, to increase awareness about cancer prevention, and to highlight progress being made in the fight against the disease. As of January 2020, more than 1,600 scientists representing more than 180 institutions are involved in SU2C-funded research projects.

Under the direction of our Scientific Advisory Committee, led by Nobel laureate Phillip A. Sharp, PhD, SU2C operates rigorous competitive review processes to identify the best research proposals to recommend for funding, oversee grants administration, and ensure collaboration across research programs.

Current members of the SU2C Council of Founders and Advisors (CFA) include Katie Couric, Sherry Lansing, Kathleen Lobb, Lisa Paulsen, Rusty Robertson, Sue Schwartz, Pamela Oas Williams, and Ellen Ziffren. The late Laura Ziskin and the late Noreen Fraser are also co-founders. Sung Poblete, PhD, RN, serves as SU2C's CEO.

 SU2C is a division of the Entertainment Industry Foundation (EIF), a 501(c)(3) charitable organization. For more information on Stand Up To Cancer, visit StandUpToCancer.org.

ABOUT EXACT SCIENCES

A provider of cancer screening and diagnostic tests, Exact Sciences pursues solutions providing the information to take life-changing action, earlier. Exact Sciences is investing in its product pipeline to take on some of the deadliest cancers and improve patient care. Exact Sciences unites collaborators to help advance the fight against cancer. For more information, please visit the company's website at ExactSciences.com, follow Exact Sciences on Twitter @ExactSciences, or find Exact Sciences on Facebook.

SU2C HEALTH EQUITY COMMITMENT STATEMENT

Stand Up To Cancer is committed to eliminating barriers of access to state of the art screening, diagnosis and treatment for all cancer patients. In doing so, with mounting evidence for the need to develop precision medical prevention, treatment and intervention solutions based on diverse patient populations, we are actively engaged in changing the health equity landscape by expanding diversity in the inclusion of historically underrepresented racial and ethnic minority populations into clinical trials that we fund. We are especially interested in supporting clinical trials and research studies that have developed successful strategies, measurable outcomes, and robust outreach plans to feasibly and effectively include these populations into these studies.

PROGRAM MISSION STATEMENT

The SU2C Colorectal Cancer Health Equity Dream Team Grant Program will foster new cancer interception research on the causes and treatments of colorectal cancer (CRC), mentor a new generation of scientists focused on CRC prevention and treatment, and provide medical professionals with tools and materials to better advocate for colon cancer screening with their patients. CRC screening and subsequent earlier detection of cancer leads to better patient outcomes, yet minority and economically disadvantaged populations suffer higher rates of advanced CRC and experience worse outcomes. Health disparities research and health delivery research has traditionally been fragmented, with research in the social sciences exploring socioeconomic and cultural barriers to access and the biological sciences studying genetic, epigenetic and environmental drivers of disease. This Dream Team requires new perspectives integrating social science and health equity domains with clinical translational research.

The goal of the Dream Team will be to create "SU2C Zones" that can operate long after the grant period is over in the neighborhoods and regions near institutions that serve minority and traditionally underrepresented populations. Efforts within the SU2C Zone will increase the screening rate for colon cancer within participating institutions' catchment areas and support innovative approaches that can be widely disseminated as a replication model throughout the US and create a foundation for CRC interception research supporting screening and therapeutic development tailored to these populations. In addition, the Dream Team will support the career development of minority physicians and scientists who embody the ideals of community engagement, trust-building and disparities research to improve health outcomes for all patients.

The Dream Team will benefit from SU2C's structure and oversight through which a multi-disciplinary team will come together with support to focus on a discrete set of aims. The six-monthly progress review practiced by SU2C ensures that milestones and deliverables are met and will keep the project focused on its goals. Moreover, the SU2C practice of integrating multidisciplinary experts on research teams, including lay patient advocates, leaders of advocacy organizations, and non-clinical research experts creates a sense of urgency among team members and results in more patient-centered clinical research. The Dream Team is supported by a transformational grant from Exact Sciences.

RESEARCH PROJECT CRITERIA

The Dream Team represents an unprecedented opportunity to bring together the best scientific minds from diverse fields of research to concentrate on new approaches to address health equity in the context of CRC interception, including screening and early detection, to reduce mortality rates and improve outcomes. Applicants will identify barriers, address prevalence in a particular population, share planned outreach, and provide evidence of previous successes in the patient population(s). Projects will be designed to increase CRC screening rates within the first two years of the grant funding period. Close collaboration between regional anchor institutions and community hospitals, Federally Qualified Health Centers, and/or rural clinics serving key medically underserved populations is required. Proposed ideas should be based on perceived opportunities for success as well as likelihood of establishing a sustainable and replicable model. A strong preference will be given to applicants that are oriented to support the career development of underrepresented minority physicians and scientists.

SU2C Zones: Applicants will define one to three SU2C Zones centered around medically-oriented anchor institutions which have commitments to consciously apply their long-term, place-based economic power of the institution, in combination with human and intellectual resources, to better the long-term welfare of local communities. Anchor institutions have significant economic, social and cultural impacts in their surrounding communities, and can play key roles in building successful community programs. The regions surrounding an anchor institution will be defined by applicants in collaboration with community-based healthcare practices and aligned advocacy organizations reflective of local communities.

Target Population: Applicants will define the target community(ies), which must include minority and traditionally underrepresented populations[1]. These definitions will include data elements that can be measured during the grant period to assess the impact of the Dream Team's activities, with the goal to demonstrate significant increase in colorectal cancer screening rates, ideally to greater than 80% of the target population(s).

APPLICATION DEADLINE

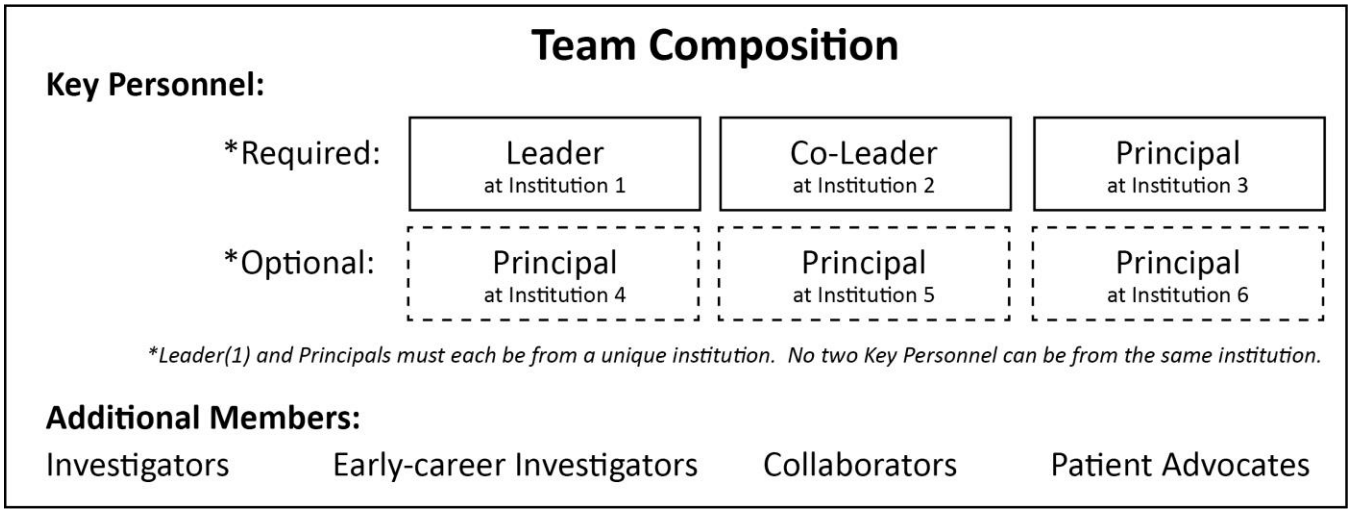
The Full Application shall be submitted by Monday, March 1, 2021, at 12:00pm noon Eastern Daylight Time at http://StandUpToCancer.org/Colorectal. The Team Leader and Co-Leader of the finalist teams will be required to present the proposal at a videoconference selection meeting to be held during the week of March 22nd, 2021. The selected team will be notified by the end of March 2021 with anticipated project start dates in June 2021.

See the section "Application Instructions" on page 9 for further information.

TEAM COMPOSITION AND MEMBER ELIGIBILITY CRITERIA

To maximize creativity, innovation, and collaboration, the Dream Team must include social and epidemiological sciences, laboratory sciences, cancer screening implementation, and clinical sciences researchers with senior and early-career investigators, some of whom have not worked together in the past. The Team will consist of a Team Leader, a Team Co-Leader, no more that four additional Team Principals, a Project Manager, and at least two Patient Advocates, ***with a minimum of three participating institutions***. Racial and ethnic diversity among Dream Team personnel is strongly encouraged, as is participation of one or more community members representing populations within the SU2C Zone.

Dream Team Composition Overview



[1] As defined by the National Institutes of Health ( ) and National Institute of Minority Health and Health Disparities (https://www.nimhd.nih.gov/about/overview/)

Definitions

1. **Team Leader (TL)** (required)**:** The Team Leader is the person responsible for the scientific and technical direction of the proposed research project, contractual and financial obligations, and other organizational assurances/certifications. The TL must ensure that the Team complies with the terms and conditions of the award, and will be the primary contact person for SU2C science staff.
2. **Lead Institution** is the organization at which the Team Leader is employed, and it will be legally and financially responsible for the conduct of Dream Team activities supported by the grant.
3. **Team Co-leader (TC)** (required)**:** A Team Co-leader is designated by the Team Leader to assist in directing the scientific and technical work of the Team. A Co-leader serves as an alternate contact person for SU2C science staff.
4. **Team Principal (TP)** (required)**:** Team Principal(s) is a senior investigator(s) who will lead a component(s)/subproject(s) of the Team research project.
5. **Project Manager** (required)**:** The Team Project Manager (PM) is the administrative leader of the Team and the key administrative contact for the Team with SU2C. The PM is responsible for the coordination of all team efforts to consistently maintain a high level of functionality, collaboration, and communication. The PM coordinates the Patient Advocates and the scientific reporting, and, where appropriate, assists the Team in developing a plan for clinical trial accrual, diversity, and tracking.
6. **Patient Advocates** (required)**:** Patient Advocates bring the perspectives of those affected by cancer (e.g., patients, survivors, caregivers) to the work of Team. They enable the Team scientists to see their research through the eyes of the target audience and integrate these perspectives into the direction of the Team research. Patient Advocate members do <u>not</u> represent the viewpoints or issues of any advocacy organization or their individual personal issues. Where appropriate, Patient Advocates also work with the Team in developing a plan for clinical trial accrual, diversity, and tracking, including measures to ensure recruitment and retention of diverse participants. If you need assistance with the identification of qualified Patient Advocates for your application, you may contact Advocacy@su2c.org.
7. **Investigators:** Senior investigators, other than the TL, TC, and TPs, who are employed at the TL, TC, or TP institutions and contribute substantively to the Team research project, may be included as members of the Team.
8. **Early-Career Investigators:** Junior faculty (i.e. independent investigators who have completed their training no more than seven years prior to the start of the grant term), postdoctoral fellows, clinical research fellows, or any other researchers-in-training who are working under the direction of a scientific mentor (i.e., a TL, TC, TP, or Investigator) may be included as members of the Team.
9. **Collaborator:** An Investigator who is not employed by a participating institution and is unfunded in this project budget yet makes valuable contributions to the Team.
10. **Budget and Contract contact** (required per institution)**:** For each participating institution/clinical trial site, provide at least two officials responsible for grant agreements.
11. **Other (Scientific/Technical):** Any person providing scientific or technical support, such as Lab managers and technicians
12. **Other (Administrative):** Any person providing administrative support such as Administrative assistants
13. **Public Information Officer (PIO)** (required per institution)**:** The PIO is the communications coordinator or spokesperson for the institution.

Team Member Eligibility Requirements

1. The TL, TC, and TPs, must have acquired a doctoral or medical degree and must be independent investigators affiliated with an academic, medical, or research institution. Individuals on the FDA Debarment List may not apply.
2. Research must be carried out within the United States. There are no citizenship or residency status restrictions for team members.

3. The TL and TC are expected to each dedicate at least 20 percent (or 40 percent combined) of their time and effort to the Team research project.
4. TPs must each dedicate at least 10 percent of their time and effort to the Team research project.
5. No Team will have more than one Key Personnel (TL, TC, or TP) from any given institution at the time of their initial appointment on the Team. No more than two Key Personnel may be from affiliated institutions. It is expected that additional Investigators from the TL, TC or TP institutions may be involved in the Team research project in some other capacity, and there is no limit to the number of Investigators from each of these institutions that may contribute to the Team project.
6. Employees or subcontractors of for-profit industry are not eligible to serve as a TL, TC, or TP; however, their participation as unfunded Collaborators is encouraged, where appropriate, to foster the development of novel strategies.
7. Early-Career Investigators are not eligible to serve as a Team Leader, Co-leader, or Principal; however, their participation in the Team research projects is highly encouraged.
8. Neither members of the SU2C Scientific Advisory Committee, SU2C Colorectal Cancer Health Equity Dream Team Selection Committee, nor members of their individual laboratories are eligible for funding as part of the SU2C Colorectal Cancer Health Equity Dream Team Grant Program.
9. Key Personnel should not be funded on more than one SU2C-sponsored Team grant (Dream Team or Research Team).
10. Except for the TL and TC, scientists may be funded concurrently on SU2C and SU2C Canada grants.
11. No more than 50 percent of the Principals (including Leader and Co-leader) from a previous Team may apply as a group on a new Team proposal.

Applicants with a question about the eligibility requirements are encouraged to contact SU2C at proposals@su2c.org prior to submitting the proposal.

EVALUATION OF PROPOSALS

The SU2C Colorectal Cancer Health Equity Dream Team Selection Committee will review the proposals for the SU2C Colorectal Cancer Health Equity Dream Team Grant Program. The Selection Committee consists of highly accomplished experts in health equity, senior laboratory researchers and physician-scientists who are respected internationally for their own accomplishments in cancer research and as leaders in the field, as well as at least two Patient Advocates.

The Selection Committee will consider the following criteria when evaluating the proposals:

- Scientific merit of the proposed research project and translational potential of the research, i.e., ultimate plan for achieving CRC screening goals as well as conducting a translational research project
- Significance of the proposed research
- Novelty of the hypothesis or methodology
- Degree to which the studies have a positive impact on the detection or treatment of cancer
- Team leadership qualities (TL, TC, TPs): Willingness to collaborate, their research credentials, their unique contributions to the Team research project, demonstrated ability to bring together and lead an interdisciplinary team of experts to a successful conclusion, expertise in the field, and commitment to translational cancer research with clear emphasis on near-term clinical application
- Involvement of patient advocates and/or community members in study design and implementation.
- A clear commitment by the Team that all data resulting from their work will be available to the scientific community at large at the earliest opportunity, as allowed under patient privacy and other applicable laws
- Likelihood that the research project will achieve its stated goals given the budget requested, institutional environments, and other resources available

- Likelihood that patient enrollment to clinical trials will be completed within the timeframe of the grant (if applicable)
- Whether the studies are designed to capitalize upon the unique populations and environments, specialized expertise, new concepts and perspectives, innovative methodologies, and/or emerging technologies that are available as a result of the multi-institutional collaboration
- Whether adequate institutional and/or financial support exists to sustain the research project
- The cost effectiveness of the budget
- Ability of participating institutions and health systems to conduct follow-up testing and care based on increased patient screening
- Liklihood of propsed model being sustainable and replicaible for CRC screening in targeted populations, based both on scientific merit and engagement with decision makers throught the project.

GRANT TERMS

Changes to application. Applicants are not allowed to change the project nor the Team members proposed in the LOI. If changes are necessary, prior written approval from SU2C is required.

Contracts. A Grant Agreement will be executed between SU2C and the Team Leader's Institution, referred to as the Lead Institution. The Lead Institution must serve as the administrator of the grant funds and hold responsibility for the disbursement of the funds, management of the budget, and provision of progress reports. It is expected that the Lead Institution will enter into subcontracts with the institutions of the Team Co-leader and Principals, and assurances that these contractual agreements have been executed will be required for continuation of funding. All contracts with industry are encouraged to use the model contract language for clinical trials of potential new cancer treatments that has been made available by the CEO Roundtable on Cancer in partnership with the NCI to comply with the requirement of the SU2C founders to expedite the negotiation process. Please visit http://transformingtrials.cancer.gov/initiatives/ctwg/standardization/highlights-start for further details.

Commencement. The Team Leader will commence upon execution of the contract agreement with the lead institution. SU2C retains the right to terminate the grant if the research project is not commenced in a timely manner.

Budget. Dream Teams may apply for total support up to $3M along with Cologuard test kits valued at $3M, over a 3-year term. The templates provided with the grant application should be used to complete a detailed budget. SU2C strongly advises a limited first year budget as past Teams over-allocated funds in the timeframe. All funding is contingent upon milestones and objectives being appropriately selected and satisfactorily pursued and achieved, as determined by SU2C and the Selection Committee.

Use of Funds. Grant funds may be used for direct research expenses attributable to the proposed research, which may include:

- A percentage of the salary and benefits expenses (limited to 20 percent of the total budget) of senior investigators
- A percentage of salary and benefits expenses of the Early-Career Investigators on the Team
- Salary and benefits expenses for research assistants or technicians
- Equipment, supplies, and other laboratory or clinical expenses
- Travel expenses relevant to the Dream Team research project, including travel to the institutions of the Team Leaders/Principals and travel to meetings with the Selection Committee, as well as to the annual SU2C Scientific Summit

- Expenses (limited to a total of $20,000/year) related to publication page charges and/or the presentation of research data at scientific meetings or through other means that will contribute to the dissemination of the scientific knowledge derived from the proposed research.

The funds may not be used for salary or benefits of any Collaborators from a government institution/agency or a for-profit industry, or for any research expenses related to the Team project that are incurred by these individuals. Tuition and professional membership dues are not allowable expenses.

Any indirect costs charged by the institutions will be negotiated to a minimum, but in no event will there be permitted a charge of more than 10 percent of the total budget.

Payments. The payment schedule between the Team and SU2C will be delineated in the contract agreement after awarding of the grant.

Reporting Requirements. Progress reports, submitted on July 15 and January 15, shall highlight the accomplishments of that specific time period bearing in mind the pre-defined Milestones and Deliverables of the Team. Progress Reports will be reviewed by SU2C and a Review Team drawn from the Selection Committee.

SU2C may withhold release of any or cancel future Grant Funds until the reports have been filed and approved. Failure to address deficiencies, meet grant requirements, or achieve the pre-defined Milestones and Deliverables may result in discontinuation of the grant.

Teams must meet three times a year, either in person, by teleconference, or videoconference, to review progress and, if necessary, adjust research plans. Two of the required can be fulfilled prior to the semi-annual reviews, where Team Leaders meet with the Review Team and all other Team members, following the submission of Progress Reports, to thoroughly discuss the Teams' progress. Review meetings schedule will be an appendix to the Team contract.

A final written progress and financial report shall be submitted no later than sixty (60) days after the ending date of the grant term. The reporting materials must include all project components.

SU2C will share copies of interim and final progress reports and may provide these materials, at their discretion, to other funders that have provided financial support for the grant, and also may use all or portions of the report for public dissemination, such as within SU2C newsletter or websites, or in other similar manners.

Publications and Acknowledgment of Support. Any publications resulting from research funded in whole or in part by the grant must cite SU2C as funders in the acknowledgment. The contract between SU2C and the Lead Institution will contain exact wording. Copies of such publications shall be forwarded to SU2C after acceptance, but before publication.

Intellectual Property. SU2C must be notified of any discovery that is protectable under applicable law (e.g. patentable), that is discovered in the course of the research funded through this grant. SU2C shall have no responsibility or interest in the protection of, commercialization or licensing of intellectual property resulting from the Team. The Team Leader and the Lead Institution shall notify SU2C of the granting of each patent or other legal protection and of all commercial exploitation of any Invention.

Insurance. Insurance shall be maintained by the Team Members and Institutions for professional liability and comprehensive general liability insurance, on an "occurrence" basis, against claims for "personal injury" liability, including bodily injury, death or property damage liability. Such insurance shall be primary and noncontributory

with any other insurance carried by SU2C and shall provide appropriate waivers of subrogation against SU2C, and its directors, committee members, employees, affiliates and agents.

Notification of Changes. It is the responsibility of the Team Leader to notify SU2C immediately of any changes in the composition of the Team, and changes in the position or institution of any of the Team Members. SU2C may not accept proposals to change the research project from that described in the application, and may terminate the grant.

Organizational Assurances. It is the responsibility of the Team Leader and Lead Institution to ensure that organizational assurances/certifications from all Team Member Institutions are obtained.
For research involving human subjects, the appropriate Team Member(s) and U.S. Institution(s) shall certify that:

a. Prior to the initiation of human research, the proposed research project has been reviewed and approved in writing by an Institutional Review Board ("IRB") constituted in accordance with current regulations promulgated by the United States Department of Health and Human Services ("HHS") and registered with HHS.

b. The Team Member(s) shall secure a legally acceptable informed consent from all human subjects taking part in any research funded in whole or in part by SU2C in accordance with and to the extent required by current regulations promulgated by the United States Department of Health and Human Services and approved by HHS. IRB approval for human subjects research should be submitted to SU2C, and funds for human subjects research will NOT be released unless and until proof of all IRB certifications is received by SU2C. Prior IRB approval for another project cannot be substituted but can be officially amended to include the proposed project.

For research involving animals, the Institution(s) shall ensure compliance with applicable chapters of the Public Health Service Animal Welfare Policy, the NIH Manual for Grants and Contracts, and any and all requirements of the Institution concerning animal welfare. Certification by the Institution Animal Care and Use Committee (IACUC) or equivalent shall be documented by submitting a copy of the institutional letter of approval, which identifies the Team Member(s) responsible for the project, the Team research project title, SU2C as the funding agencies, and the date of approval, and is signed by the IACUC Chair or equivalent Institution official. Prior IACUC certification for another project cannot be substituted, but can be officially amended to include the proposed project.

Team Members at non-U.S. institutions must adhere to ethical standards for the protection of human and animal subjects that are at least equivalent to U.S. standards, and to the legal requirements of the country of origin. Certification of ethical standards review and approval should be documented by submitting a letter, which cites all relevant approval and license numbers and dates required by the country of origin. In the absence of an official ethical review board (or equivalent) or legal requirements, the Team Member(s) must agree in writing to adhere at minimum to the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects.

APPLICATION INSTRUCTIONS

APPLICATIONS

Applications must be submitted on or before noon Eastern Daylight Time on **Monday, March 1st, 2021**, to http://StandUpToCancer.org/Colorectal. The application includes both (1) a text application template and (2) spreadsheet templates for completion and submission. The application templates will be provided to teams selected to submit Full Applications. Instructions are available in the templates.

The application includes the following sections:

Application Template

- Title Page
- Signatures Pages: Signature pages must be submitted for every Institution requesting SU2C Health Equity Breakthrough Team funds through this grant application. The Team Leader, Team Co-Leader, every Team Principal, and Patient Advocate(s) must be included in the Signature Pages.
- Lay Abstract (limited to 1/2 page)
- Scientific Abstract (limited to 1/2 page)
- Research Proposal (limited to -20 pages; include the following information)
    - Background and Rationale
    - Specific Aims
    - Research Design and Methods
    - Statistical Plan
    - Projected Timeline and Milestones
    - Significance and Therapeutic Impact
    - Collaboration/Team Members
    - Data Sharing Plan
    - Patient Advocate Role
    - Demonstrated experience in proven success in relevant patient populations
    - Recruitment and Retention Plan
- Facilities (limited to 1 page per Institution)
- References (no page limit)
- Other Support
- Budget Justification: Limited to three (3) pages per institution. Detailed justification of the separate budget requests for expenses related to the research components/subprojects conducted by the Team leader, Team Co-Leader, and Team Principals is required for all items of the equipment costing over $1,000, and the need for personnel, supplies, and other items. Provide the names of individuals whose salaries will be supported by the grant funds and justify the amount of support requested. If requesting "Other Expenses," a thorough list of these expenses along with the justification is required.

Appendix

- Milestones and Deliverables Timeline (Tab A in Spreadsheet Templates)
- Requested funding and required regulatory approvals per Specific Aim (Tab B in Spreadsheet Templates) and Clinical Trials (Tab B.1 in Spreadsheet Templates)
- Budget (should not exceed 6.0 million USD): See sections "Budget" and "Use of Funds" on p. 5-6 for additional information.
    - Total Budget per Year (Tab C1 in Spreadsheet Templates)
    - Budget per Institution (Tab C2 in Spreadsheet Templates; complete for every institution)

    - Total Budget per Institution (Tab C3 in Spreadsheet Templates"
- Personnel Tracker (Tab D in Spreadsheet Templates): See section "Eligibility Criteria" on p. 2-4 for additional information.
- CVs for Team Leadership (Team Leader, Team Co-Leader, Team Principals; NIH Biosketch preferred but not required; no template is provided; do not exceed five (5) pages per individuals)
- Letters of Support
    - Letters from Leadership at each Institution involved in the Team
    - Letters from other Company(ies) collaborating with the Team
    - Letter(s) from the Chief Diversity Officer (or equivalent) at the Lead Institution as well as each Institution involved in patient recruitment or care for Team clincial trials
- Clinical Trial Protocol (if a clinical trial is proposed)
    - The Clinical Trial Protocol must include the following in no particular order (CTEP guidance may be followed https://ctep.cancer.gov/protocoldevelopment/templates_applications.htm):
        - Study Rationale: Provide a brief description of the medical question and the rationale of how this trial addresses the question. Provide a rationale for the dose schedule outlined for all treatment arms. Reference any non-labeled indication.
        - Primary Objective: Provide the main goal of the study and the study population. Provide a detailed definition that is directly linked to the primary objective. In some cases, the detailed description may be more appropriate in the statistical section.
        - Primary Endpoint
    - Primary Endpoint
    - Hypothesis
    - Study Assessments: Specify type and frequency of safety, efficacy, and outcome measures. Also indicate the method(s) used to assess measures.
    - Secondary Objective
    - Data and Statistical Plan: Describe the planned statistical analysis including timing of the primary and secondary measurements and sample size calculation. The range of sophistication will depend on a number of factors, including the size and complexity of the study. Indicate how incidence of the cancer(s) in the relevant patient population(s) will be reflected in the analysis of the sample data.
    - References: List references, studies, and sources that support the study design.
    - Targeted Patient Population: Specify age, gender, diversity, and other demographic information for the trial population.
    - Recruitment and Retention Plan : Specify approach to accrue representative patient population to the trial. Provide patient recruitment and retention plan addressing methods to ensure appropriate representation of historically underrepresented racial and ethnic minority populations.
    - Specify the dose, schedule, duration, and any pre-medications, etc.
    - Sample Size Calculation
    - Sample Size Justification: The sample size must reference the primary endpoint.
    - List any correlative studies.
    - Key Inclusion and Exclusion Criteria: List all inclusion and exclusion criteria necessary to support the trial design and drug safety requirements.
    - Secondary Endpoint
    - Data Handling and Record Keeping including a formal Data Use Agreement

Other Application Information

The spreadsheet templates include: (1) Milestones and Deliverables Timeline, (2) Requested funding and required regulatory approvals per Specific Aim, (3) Budget per year and per Institution, and (4) Personnel Tracker. Collaborative groups of researchers from diverse institutions are preferred; all applications must

include inter-institutional collaborations. Curriculum vitae (NIH Biosketch preferred but not required) with a recent (five year) publication list as well as current funding should be included for Team Leadership (Team Leader, Team Co-Leader, and Team Principals). Teams are required to have a Team Leader and a Team Co-Leader. Teams must include a Project Manager and at least two Patient Advocates. Projects should be planned for four years, with any proposed trials completing accrual by the end of the grant period. The proposed budget should not exceed 6 million US dollars total. If a clinical trial is proposed, then a clinical trial protocol or a compelling justification for delaying the protocol development will be required.

Application Submission
The application submission site is available at StandUpToCancer.org/BreakthroughTeam. An email will be sent to confirm receipt of your online submission.

Changes to the Application
Following the submission of an application, the Team Leader should notify SU2C in writing of (1) any changes of address, email, or phone number for any Team member, (2) any changes in institution for any Team member, or (3) withdrawal of the application for any reason.

Notification. The Full Application shall be submitted by Monday, March 1, 2021, at 12:00pm noon Eastern Daylight Time at http://StandUpToCancer.org/Colorectal. The Team Leader and Co-Leader of the finalist teams will be required to present the proposal at a videoconference selection meeting to be held during the week of March 22nd, 2021. The selected team will be notified by the end of March 2021 with anticipated project start dates in June 2021.

INQUIRIES
Inquiries about the program guidelines, eligibility requirements, and application materials can be directed to the SU2C Science Office at:

Phone: 832-684-6462
Email: proposals@su2c.org