Stand Up To Cancer – Cancer Research UK
Pediatric Brain Cancer Dream Team
Translational Research Grant

Program Guidelines and Application Instructions
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ABOUT STAND UP TO CANCER

Stand Up To Cancer (SU2C) was created through an unprecedented collaboration uniting the major television networks, entertainment industry executives and celebrities, and prominent leaders in cancer research and patient advocacy. SU2C believes that the last thirty years have brought about a revolution in our understanding of the origins and causes of cancer. Today’s cancer scientists are now on the verge of translating these scientific discoveries into new, life-saving strategies to prevent, diagnose, or treat cancer. SU2C embarked on a series of projects to raise significant dollars to fund cancer research that will positively impact patient care and prevention. These projects included five internationally televised events, which aired on September 5, 2008, September 10, 2010, September 7, 2012, September 5, 2014, and most recently, September 9, 2016 that was aired simultaneously on several major networks. The funds raised through this and other SU2C efforts are supporting translational cancer research Dream Teams, Translational Teams, and the SU2C Innovative Research Grants.

ABOUT CANCER RESEARCH UK

Our vision is to bring forward the day when all cancers are cured. In our research strategy we’ve outlined our ambition to accelerate the progress of cancer research over the next 20 years, so that by 2034 three in four people diagnosed with cancer will survive for at least ten years. We will achieve our ambitions by funding a broad range of high quality research to help us better understand, prevent, diagnose and treat cancer.

PROGRAM MISSION STATEMENT

The Stand Up To Cancer - Cancer Research UK Pediatric Brain Cancer Dream Team Translational Research Grant represents a focused effort to implement advances in cancer research as rapidly as possible through the creation of a collaborative, translational, cancer research "Dream Team." The most talented and promising researchers across institutions will be assembled into a Dream Team, forming an optimal configuration of expertise needed to solve key problems in cancer and positively impact patients in the near future. This Dream Team will span multiple disciplines and utilize the new tools of modern biology to attack research questions in a coordinated way. Mechanisms to foster collaborations within and among the Dream Teams will be employed – an approach that promotes the sharing of information and a goal-oriented focus on measurable milestones of progress. SU2C and Cancer Research UK believe that this unique Dream Team model will advance scientific research in the interests of both today’s cancer patients and those who may develop cancer in the future.

The grant will provide up to $10 million in funding over a 4-year grant term, depending upon project requirements, and will be contingent on the SU2C-CRUK Joint Scientific Advisory Committee (JSAC) finding that the funds are justified and that milestones and objectives have been appropriately selected and are being satisfactorily pursued and achieved.
APPLICATION DEADLINE

An Intent to Submit an application for the Stand Up To Cancer – Cancer Research UK Pediatric Brain Cancer Dream Team Translational Research Grant must be submitted by Monday, July 2, 2018, at 12:00pm noon Eastern Daylight Time to proposals@su2c.org. See page 10 for further Application Instructions.

Full Proposals for the Stand Up To Cancer – Cancer Research UK Pediatric Brain Cancer Dream Team Translational Research Grant must be submitted by Monday, August 13, 2018, at 12:00pm noon Eastern Daylight Time at StandUpToCancer.org/DreamTeamApplication. See page 10 for further Application Instructions.

RESEARCH PROJECT CRITERIA

The SU2C-CRUK Pediatric Brain Cancer Dream Team Translational Research Grant in pediatric (age range up to 18 years) brain cancer will fund a translational cancer research project that will address critical problems in patient care, including prevention strategies for those at risk, and deliver near-term patient benefit through investigation by a multidisciplinary, multi-institutional, collaborative Dream Team of expert investigators. The ideas may focus on innovative methods of treatment, diagnostic or imaging techniques, or factors that contribute to development and progression. Projects must be designed to accelerate the application of new preventive, diagnostic or therapeutic approaches to the clinic (i.e., lead to patient involvement within 2-3 years from the beginning of the grant). Proposals for Dream Team research projects must present plans indicating how the work will be translated into the clinic. Research proposals may incorporate issues dealing with survivorship and long-term effects on patients. Projects should have a strong clinical focus. The ideas should be based on perceived opportunities for success as well as high-priority areas with a critical need for rapid progress beyond current medical care.

DREAM TEAM COMPOSITION AND MEMBER ELIGIBILITY CRITERIA

To maximize creativity, innovation, and collaboration, the Dream Team must include laboratory and clinical researchers, senior and/or young investigators, and senior scientists who have not worked together in the past.

Dream Team Composition Overview

<table>
<thead>
<tr>
<th>Key Personnel:</th>
<th>Leader (at institution 1)</th>
<th>Co-leader or Principal (at institution 2)</th>
<th>Principal (at institution 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Required</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Optional</td>
<td>Principal (at institution 4)</td>
<td>Principal (at institution 5)</td>
<td>Principal (at institution 6)</td>
</tr>
</tbody>
</table>

*Leader (1), Co-Leader (1), and Principals must each be from a unique institution. No two Key Personnel can be from the same institution.

Additional Members:
- Investigators
- Young Investigators
- Collaborators
- Advocates (2)
Definitions.

**Dream Team Leader (DTL).** The Dream 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 DTL must ensure that the Team complies with the terms and conditions of the award, and will be the primary contact person for SU2C Scientific staff.

**Dream Team Co-leader (DTC).** A Dream Team Co-leader is designated by the Dream 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 Scientific staff.

**Dream Team Principals (DTPs).** Dream Team Principals are senior investigators who will lead a component(s)/subproject(s) of the Dream Team research project.

**Dream Team Project Manager.** The Dream Team Project Manager (PM) is the administrative leader of the Dream Team and the key administrative contact for the Team with Stand Up To Cancer and Cancer Research UK. The PM is responsible for the coordination of all team efforts to consistently maintain a high level of functionality, collaboration, and communication.

**Patient Advocates.** Patient Advocates bring the perspectives of those affected by cancer (e.g., patients, survivors, caregivers) to the work of Dream Team. They enable the Dream Team scientists to see their research through the eyes of the target audience and integrate these perspectives into the direction of the Dream Team research. Patient Advocate members do not represent the viewpoints or issues of any advocacy organization or their individual personal issues. If you need assistance with the identification of qualified Patient Advocates for your application, you may contact Advocacy@su2c.org.

**Investigators.** Senior investigators, other than the DTLs, Dream Team Co-leaders, and DTPs, who are employed at the DTL’s, Dream Team Co-leader’s, or DTP’s institutions and contribute substantively to the Dream Team research project, may be included as members of the Dream Team.

**Young Investigators.** Junior faculty (i.e. independent investigators who have completed their training no more than five 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 DTL, Co-Leader, DTP, or Investigator) may be included as members of the Dream Team.

**Collaborators.** These are senior investigators who are employees or subcontractors of a government institution/agency or a for-profit industry, and who could make valuable contributions to the Dream Team research project. A Collaborator also may be an individual from an academic, medical, or research institution not receiving SU2C grant funds.

Each Team will consist of a Dream Team Leader, a Dream Team Co-leader, no more than four additional Dream Team Principals, a Project Manager, and at least two Patient Advocates, with a minimum of three participating institutions:

- The DTL, DTCs and DTPs, must have acquired a doctoral or medical degree and must be independent investigators affiliated with an academic, medical, or research institution.

- There are no citizenship or residency status restrictions for team members; however, the DTL or a DTC must be UK-based.
• The DTL and DTCs are expected to each dedicate at least 20 percent (or 40 percent combined) of their time and effort to the Dream Team research project.

• DTPs must each dedicate at least 10 percent of their time and effort to the Dream Team research project.

• No Dream Team will have more than one Key Personnel (DTL, DTC, or DTP) 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 DTL’s, DTC’s or DTP’s institutions may be involved in the Dream 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 Dream Team project.

• Employees or subcontractors of for-profit industry are not eligible to serve as a DTL, DTC, or DTP, however their participation as Collaborators is encouraged, where appropriate, to foster the development of novel diagnostic and treatment strategies.

• Young Investigators are not eligible to serve as a Dream Team Leader, Co-leader, or Principal; however, their participation in the Dream Team research projects is encouraged.

• Neither members of the SU2C-CRUK JSAC nor members of their individual laboratories are eligible for funding as part of the Stand Up To Cancer – Cancer Research UK Pediatric Brain Cancer Dream Team Translational Research Grant.

• Key Personnel should not be funded on more than one SU2C-sponsored Dream Team grant.

• Except for the DTL and DTC, scientists may be funded concurrently on SU2C and SU2C Canada grants.

• No more than 50 percent of the Principals (including Leader and Co-leader) from a previous Dream Team may apply as a group on a new Dream Team proposal.

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

**EVALUATION OF PROPOSALS**

The JSAC will review the proposals for the Stand Up To Cancer – Cancer Research UK Pediatric Brain Cancer Dream Team Translational Research Grant. The Committee consists of highly accomplished 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 JSAC will consider the following criteria when evaluating the proposals:
• Scientific merit of the proposed research project and translational nature of the research, i.e., plan for translating the work from the laboratory to the clinic to deliver near-term patient benefit (lead to patient involvement within 24-36 months);

• Significance of the proposed research, i.e., whether it addresses a critical need for rapid progress beyond current medical care for pediatric brain cancer patients;

• Novelty of the hypothesis or methodology;

• Degree to which the studies will have a positive clinical impact on the prevention, detection, or treatment of pediatric brain cancer;

• Dream Team Leader’s vision, leadership qualities, willingness to collaborate, 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 a clear emphasis on near-term clinical application;

• Willingness of the Dream Team Leader, Co-leader, and Principals to collaborate, their research credentials, and their unique contributions to the Dream Team research project;

• A clear commitment by the Dream Team that all data resulting from their work will be available to the scientific community at large at the earliest opportunity;

• Likelihood that the research project will achieve its stated goals given the budget requested, institutional environments, and other resources available;

• 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 due to the multi-institutional collaboration; and

• Whether adequate institutional and/or financial support exists to sustain the research project.

GRANT TERMS

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

Contracts. A Grant Agreement will be executed between SU2C and the Dream 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 Dream 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 Dream 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 of up to $10 million over a 4-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 JSAC.

**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 (not UK-based) on the Dream Team (i.e., Leader, Co-Leader(s), Principals, and/or Senior Investigators within each of the collaborating institutions). Salary and benefits may not be applied for UK-based senior investigators;
- No funds for should be used for salary and benefits of key personnel already supported on CRUK grants.
- A percentage of salary and benefits expenses of the Young 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 Dream Team Leaders/ Principals and travel to meetings with the JSAC, as well as to the annual SU2C Scientific Summit and the AACR Annual Meeting; and
- 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 Dream 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. No indirect or directly allocated costs should be charged on any activity taking place in the UK.

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

**Reporting Requirements.** Progress reports, submitted on June 15 and December 15, should highlight the accomplishments of that specific time period bearing in mind the pre-defined Milestones and Deliverables of the Dream Team. Progress Reports will be reviewed by SU2C, CRUK, and a Review Team drawn from the JSAC.
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.

Dream 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 Dream 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 Dream 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.

SU2C, at its discretion, may provide copies of interim and final progress reports to the funder that has provided financial support for the grant, and also may use all or portions of the report for public dissemination, such as within a 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 and CRUK as funders in the acknowledgment. The contract between SU2C and the Lead Institution will contain exact wording. Copies of such publications must 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 Dream Team. CRUK reserves the right to review intellectual property resulting from the activity of UK-based members of the Dream Team. The Dream 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 Dream 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 CRUK or SU2C and shall provide appropriate waivers of subrogation against CRUK and SU2C, and its directors, committee members, employees, affiliates and agents.

Notification of Changes. It is the responsibility of the Dream Team Leader to notify SU2C and CRUK immediately of any changes in the composition of the Dream Team, and changes in the position or institution of any of the Dream 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 Dream Team Leader and Lead Institution to ensure that organizational assurances/certifications from all Dream Team Member Institutions are obtained.
For research involving human subjects, the appropriate Dream 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 Dream 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 Dream Team Member(s) responsible for the project, the Dream Team research project title, SU2C and CRUK 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.

Dream 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 Dream 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

Intent to Submit a Proposal
The intent to submit a proposal template should be downloaded from the StandUpToCancer.org/DreamTeamApplication and emailed to proposals@su2c.org by 12:00 pm noon Eastern Daylight Time on Monday, July 2, 2018. An email confirming receipt will be generated.

Full Proposal
The application includes both (1) a text application template and (2) spreadsheet templates for completion and submission. 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-CRUK Pediatric Brain Cancer 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)
  o Background and Rationale
  o Specific Aims
  o Research Design and Methods
  o Statistical Plan
  o Projected Timeline and Milestones
  o Significance and Therapeutic Impact
  o Collaboration/Team Members
  o Data Sharing Plan
  o Patient Advocate Role

• 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 10 million US dollars total): See sections “Budget” and “Use of Funds” on p. 6-7 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 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
• 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
    - 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.

- References: List references, studies, and sources that support the study design.
- Targeted Patient Population: Specify age, gender, and other demographic information for the trial population.
- Specify the dose, schedule, duration, and any pre-medications, etc.
- Participating Countries
- 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

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 scale of a project should not exceed 10 million US dollars total. Letters of Support from leadership at each institution and company involved with the Team are required. 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/DreamTeamApplication. 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.

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