

**Application**

**Pediatric SU2C Catalyst®**

Date Submitted:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***All highlighted areas in this template are for application instructions and may be deleted in the final version.***

**Please refer to “Program Guidelines and Application Instructions” for further details about the application procedure.**

Formatting Guidelines:

* Must use 11 point Calibri for the text, and no smaller than 9 point type for figures, legends, and tables.
* Single-spaced text is acceptable, and space between paragraphs is recommended.
* The page margins must be no less than 0.75 inches on each side.
* Pages must be numbered consecutively; in the Proposal Narrative, do not use section designations such as "3A" or "3B."

***Insert Project Title***

**Team Leader (Select one: Pre-clinical, Clinical, or Translational; If the project involves a Clinical component, then a Clinical Leader must be identified.)**

**First name Last name, Degree**

Title/Position:

Institution:

Department:

Email:

Phone:

Reporting line to Institution Head of Research:

**Team Co-Leader (Select another: Pre-clinical, Clinical, or Translational; If the project involves a Clinical component, then a Clinical Leader must be identified.)**

**First name Last name, Degree**

Title/Position:

Institution:

Department:

Email:

Phone:

**Project Manager**

**First name Last name, Degree**

Title/Position:

Institution:

Department:

Email:

Phone:

Supervisor:

**Drugs to be used in this project (identify the indication):**

**Companies to be involved in this project:**

**List all Institutions involved in this project:**

**Clinical trial sites to be involved in this project (identify the lead clinical trial site):**

**Who will the IND holder for this clinical trial be?**

**What is the planned duration for the clinical trial (# months)?**

**What is the planned start date for the project and for the clinical trial?**

**Will this project fund pre-clinical research, a clincial trial, and/or translational research?**

**Total Budget for this project:**

**TABLE OF CONTENTS (Insert page numbers below)**

Title of Research Project (limited to 75 characters including spaces) 1

I. Signatures Pages

II. Lay Abstract (limited to 1/2 page)

III. Scientific Abstract (limited to 1/2 page)

IV. Research Proposal (limited to 3 pages; include the following information)

1. Background and Rationale
2. Specific Aims
3. Research Design and Methods
4. Statistical Plan
5. Projected Timeline and Milestones
6. Significance and Therapeutic Impact
7. Collaboration/Team Members
8. Data Sharing
9. Advocacy

V. Facilities (limited to 1 page per institution)

VI. References (no page limit)

VII. Other Support

VIII. Budget Justification

**APPENDIX**

A. Milestones and Deliverables Timeline

B. Specific Aim Funding and Regulatory Approvals

C. Budget (should not exceed 3 million dollars total)

 1. Total Budget per Year

 2. Budget per Institution

 3. Total Budget per Institution

D. Personnel Tracker

E. CVs for Team Leadership (Team Leader, Team Co-Leader, Team Principals)

F. Letters of Support

 1. Letters from Leadership at each Institution involved in the Team

 2. Letters from other Company(ies) collaborating with the Team

G. 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>):

1. 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.
2. 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.
3. Primary Endpoint
4. Hypothesis
5. Study Assessments: Specify type and frequency of safety, efficacy, and outcome measures. Also indicate the method(s) used to assess measures.
6. Secondary Objective
7. 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.
8. References: List references, studies, and sources that support the study design.
9. Targeted Patient Population: Specify age, gender, and other demographic information for the trial population.
10. Specify the dose, schedule, duration, and any pre-medications, etc.
11. Participating Countries
12. Sample Size Calculation
13. Sample Size Justification: The sample size must reference the primary endpoint.
14. List any correlative studies.
15. Key Inclusion Criteria: List the inclusion criteria necessary to support the trial design and drug safety requirements.
16. Key Exclusion Criteria: List the exclusion criteria necessary to support the trial design and drug safety requirements.
17. Secondary Endpoint
18. Data Handling and Record Keeping

**I. SIGNATURE PAGES (Required for Team Leader, Team Co-Leader, Team Principal(s), and Patient Advocate(s))**

|  |
| --- |
| **Pediatric SU2C Catalyst Research Grant****Team Leader and Lead Institution Signature Page** |
| **A. TITLE OF RESEARCH PROJECT** *(Do not exceed 75 characters, including spaces and punctuation.)*  |
| **B. TEAM LEADER** (Primary Contact Person) |
| NAME: *(last, first, middle)* |
| POSITION TITLE:  |
| DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT:  |
| MAILING ADDRESS: *(Street, city, state, zip code)*  |
| EMAIL ADDRESS: |
| TELEPHONE: | FAX: |
| ASSISTANT’S NAME: |
| TELEPHONE:  | EMAIL:  |
| **C. CERTIFICATION AND ACCEPTANCE:** *By signing, I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with SU2C terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.*  | **SIGNATURE OF INDIVIDUAL NAMED IN B:***(In blue ink. “Per” signature not acceptable.)* | **DATE:** |
| **D. LEAD INSTITUTION** (Team Leader Institution) |
| Institution:  |
| Main Address:   |
| **E. ADMINISTRATIVE OFFICIAL AT LEAD INSTITUTION TO BE NOTIFIED IF AWARD IS MADE** | **F. OFFICIAL SIGNING FOR LEAD INSTITUTION** |
| Name: |   | Name: |   |
| Title: |   | Title:  |   |
| Address: |   | Address: |   |
| TELEPHONE: |   | FAX: |   | TELEPHONE: |   | FAX: |   |
| EMAIL: |   | EMAIL: |   |
| **F. LEAD INSTITUTION CERTIFICATION AND ACCEPTANCE:**  *I certify that the statements herein are true, complete, and accurate to the best of my knowledge, and accept the obligation to comply with SU2C terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.* | **SIGNATURE OF OFFICIAL NAMED IN E:***(In blue ink. “Per” signature not acceptable.)* | **DATE:**  |

**Signature Pages Required for Team Leader, Team Co-Leader, Team Principal(s), and Patient Advocate(s)**

|  |
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| **Pediatric SU2C Catalyst Research Grant****Team Co-Leader and Institution Signature Page** |
| **A. TITLE OF RESEARCH PROJECT** *(Do not exceed 75 characters, including spaces and punctuation.)*  |
| **B. TEAM CO-LEADER**  |
| NAME: *(last, first, middle)* |
| POSITION TITLE:  |
| DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT:  |
| MAILING ADDRESS: *(Street, city, state, zip code)*  |
| EMAIL ADDRESS: |
| TELEPHONE: | FAX: |
| ASSISTANT’S NAME: |
| TELEPHONE:  | EMAIL:  |
| **C. CERTIFICATION AND ACCEPTANCE:** *By signing, I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with SU2C terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.*  | **SIGNATURE OF INDIVIDUAL NAMED IN B:***(In blue ink. “Per” signature not acceptable.)* | **DATE:** |
| **D. INSTITUTION** (Co-Leader's Institution) |
| Institution:  |
| Main Address:   |
| **E. ADMINISTRATIVE OFFICIAL AT LEAD INSTITUTION TO BE NOTIFIED IF AWARD IS MADE** | **F. OFFICIAL SIGNING FOR LEAD INSTITUTION** |
| Name: |   | Name: |   |
| Title: |   | Title:  |   |
| Address: |   | Address: |   |
| TELEPHONE: |   | FAX: |   | TELEPHONE: |   | FAX: |   |
| EMAIL: |   | EMAIL: |   |
| **F. INSTITUTION CERTIFICATION AND ACCEPTANCE:**  *I certify that the statements herein are true, complete, and accurate to the best of my knowledge, and accept the obligation to comply with SU2C terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.* | **SIGNATURE OF OFFICIAL NAMED IN E:***(In blue ink. “Per” signature not acceptable.)* | **DATE:**  |

**Signature Pages Required for Team Leader, Team Co-Leader, Team Principal(s), and Patient Advocate(s)**

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| **Pediatric SU2C Catalyst Research Grant****Team Principal and Institution Signature Page** |
| **A. TITLE OF RESEARCH PROJECT** *(Do not exceed 75 characters, including spaces and punctuation.)*  |
| **B. TEAM PRINCIPAL** (Primary Contact Person at Institution) |
| NAME: *(last, first, middle)* |
| POSITION TITLE:  |
| DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT:  |
| MAILING ADDRESS: *(Street, city, state, zip code)*  |
| EMAIL ADDRESS: |
| TELEPHONE: | FAX: |
| ASSISTANT’S NAME: |
| TELEPHONE:  | EMAIL:  |
| **C. CERTIFICATION AND ACCEPTANCE:** *By signing, I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with SU2C terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.*  | **SIGNATURE OF INDIVIDUAL NAMED IN B:***(In blue ink. “Per” signature not acceptable.)* | **DATE:** |
| **D. INSTITUTION** (Team Principal’s Institution) |
| Institution:  |
| Main Address:   |
| **E. ADMINISTRATIVE OFFICIAL AT LEAD INSTITUTION TO BE NOTIFIED IF AWARD IS MADE** | **F. OFFICIAL SIGNING FOR LEAD INSTITUTION** |
| Name: |   | Name: |   |
| Title: |   | Title:  |   |
| Address: |   | Address: |   |
| TELEPHONE: |   | FAX: |   | TELEPHONE: |   | FAX: |   |
| EMAIL: |   | EMAIL: |   |
| **F. INSTITUTION CERTIFICATION AND ACCEPTANCE:**  *I certify that the statements herein are true, complete, and accurate to the best of my knowledge, and accept the obligation to comply with SU2C terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.* | **SIGNATURE OF OFFICIAL NAMED IN E:***(In blue ink. “Per” signature not acceptable.)* | **DATE:**  |

**Signature Pages Required for Team Leader, Team Co-Leader, Team Principal(s), and Patient Advocate(s)**

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| **Pediatric SU2C Catalyst Research Grant****Patient Advocate Signature Page** |
| **A. TITLE OF RESEARCH PROJECT** *(Do not exceed 75 characters, including spaces and punctuation.)*  |
| **B. ADVOCATE**  |
| NAME: *(last, first, middle)* |
| POSITION TITLE:  |
| DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT:  |
| MAILING ADDRESS: *(Street, city, state, zip code)*  |
| EMAIL ADDRESS: |
| TELEPHONE: | FAX: |
| ASSISTANT’S NAME: |
| TELEPHONE:  | EMAIL:  |
| **C. CERTIFICATION AND ACCEPTANCE:** *By signing, I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with SU2C terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.*  | **SIGNATURE OF INDIVIDUAL NAMED IN B:***(In blue ink. “Per” signature not acceptable.)* | **DATE:** |

**II. LAY ABSTRACT OF RESEARCH PROPOSAL**

This abstract, limited to 1/2 page, should provide a clear, concise overview of the proposed research. Include language suitable for a non-scientific audience. Describe relevance of the proposed work to the goals of Stand Up To Cancer. Abbreviations should only be used if necessary and should be defined appropriately.

**III. SCIENTIFIC ABSTRACT OF RESEARCH PROPOSAL**

Must not exceed 1/2 page. Should provide a clear, concise overview of the proposed work, including the background,objective, hypothesis and its supporting rationale; specific aims of the study; study design; and clinical impact and significance of the proposed work. For any clinical trial involved in this project, include a summary of the trial with key protocol elements. Refrain from using proprietary information as the scientific abstract could become public information.

**IV. RESEARCH PROPOSAL (Sections 1-8)**

Limited to 3 pages, including figures and tables. Describe the proposed research project, including:

1) Background and Rationale

2) Specific Aims State the hypotheses being addressed and the corresponding objectives.

3) Research Design and Methods For pre-clinical and translational research: Include the experiments per Specific Aim, including models or clinical samples to be used. For Clinical Trial: State the type of experimental design (observational or interventional; crossover etc.); clinical dosage, dosage form, route, and dose regimen; correlative biomarkers, PK, etc. Pediatric SU2C Catalyst projects must involve a clinical trial in some way: (1) How will a clinical trial be involved in this project? (2) What are the logistics for the clinical trial? (3) What barriers exist that would delay the start of the trial? (4) Will a CRO or consortium be involved? How will this entity be integrated with the team? What is the cost associated with this entity? Have the details of the logistics been worked out with the entity? (5) If the clinical trial is sponsored by other funds, how will it be integrated with this project? (6) How many patients will be included in this clinical trial? (7) How will GCP be handled? (8) Please provide the clinical trial protocol in the Appendix. If a protocol is not included with the application, provide a compelling justification for the omission.

4) Statistical Plan Include justification for clinical sample size and primary hypothesis testing.

5) Projected Timeline and Milestones Provide a sequence or timetable for the project and identify the milestones by which the success of the proposed research will be measured. Given that Pediatric SU2C Catalyst projects are intended to be collaborative as well as nimble (ready to begin the research upon award), indicate what specific aims will be ready to begin upon award. Include the timeline for securing regulatory approvals. Be sure the Milestones and Deliverables spreadsheet is consistent with this section.

6) Significance and Therapeutic Impact If the specific aims are achieved, state how clinical practice will be advanced. Please indicate how this project meets an unmet need or health disparity.

7) Collaboration/Team Members Describe the value-added activities of each team and/or unique benefits afforded by the collaboration and the plan for coordinating the research across the multiple Institutions. Indicate how team members are already working together to ensure initiation of research as soon as possible following award. Indicate how the team has already worked with industry collaborators to ensure smooth initiation of the research (CDA, MTA, CTA, scientific approval, clinical approval, etc.).

8) Data Sharing Describe how data resulting from this project will be available to the scientific community at large at the earliest opportunity, as allowed under patient privacy and other applicable laws.

9) Advocacy Describe how the Patient Advocate will be involved in the project. Identify advocacy organizations relevant to the cancer type(s) associated with this project.

**V. FACILITIES**

Limited to 1 page per institution. Please provide a description of the research facilities, equipment and other resources available for this project.

**VI. REFERENCES**

List references cited in the Proposal Narrative. There is no page limit for References.

**VII. Other Support**

Provide details of any current funding or funding applications in progress to support any component/subproject of the proposed SU2C Catalyst research project.

1. List funding that has been secured by the Principal Investigator or Key Personnel for the grant term. If not applicable, type “N/A” into the first field.

| **Granting Agency** | **Principal Investigator** | **Name of Grant** | **Project Description (Goals/Specific Aims)** | **Amount** | **Start Date-End Date** |
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1. List other funding for which the Principal Investigator or Key Personnel has applied. If not applicable, type “N/A” into the first field.

| **Granting Agency** | **Principal Investigator** | **Name of Grant** | **Project Description (Goals/Specific Aims)** | **Amount** | **Estimated Start Date-End Date** |
| --- | --- | --- | --- | --- | --- |
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**VIII. BUDGET JUSTIFICATION**

Detailed justification of the separate budget requests for expenses related to the research components/subprojects conducted by each of the Principal Investigator and Key Personnel is required for all items of equipment costing over $1,000, and the need for personnel, supplies, and other items. Limited to 3 pages per institution.

A. Personnel Provide the names of individuals whose salaries will be supported by the grant funds and justify the amount of support requested. **Provide % effort and % salary requested.** Please be sure this list is consistent with the Team Personnel Tracker.

B. Direct Costs, Non-Personnel, including Equipment, Supplies, Consortium/Contractual Expenses

C. Travel Expenses Directly Related to the Collaboration

D. Patient Care Costs, Inpatient and/or Outpatient

E. Recruitment and Retention Costs Provide fees associated with recruiting and retaining clinical trial participants (web site, flyers, communications, etc.).

F. Expenses Related to Publication Page Charges and/or the Presentation of Research Data at Scientific Meetings or Through Other Means.

G. Other Expenses Provide specific details about the other expenses.

H. Indirect Costs Corresponding to what is typically negotiated for industry support at each Institution; indirect costs may not exceed 25% of the total budget**.**