

Stand Up To Cancer Dream Team Translational Research Grant

Program Guidelines and Application Instructions



SCIENTIFIC PARTNER OF STAND UP TO CANCER

615 Chestnut Street, 17th Floor Philadelphia, PA 19106-4404 (215) 440-9300; (215) 440-9322 (FAX) su2c@aacr.org; www.aacr.org

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PROGRAM GUIDELINES

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.

As the scientific partner in the SU2C initiative, the American Association for Cancer Research (AACR) provides scientific oversight and conducts expert peer review and grants administration for SU2C. The AACR is highly regarded as the scientific brain trust in all subfields of cancer research and for its peer review process that is fast, flexible, rigorous, and transparent.

PROGRAM MISSION STATEMENT

The **Stand Up To Cancer Dream Team Translational Research Grant** represents a new, 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 believes 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 3-year grant term, depending upon project requirements, and will be contingent on the SU2C Scientific Advisory Committee (SAC) finding that the funds are justified and that milestones and objectives have been appropriately selected and are being satisfactorily pursued and achieved.

APPLICATION DEADLINE

A Letter of Intent (LOI) for the Stand Up To Cancer Dream Team Translational Research Grant must be submitted by **Tuesday, September 5, 2017**. See page 10 for further Application Instructions.

Invited Full Proposals for the Stand Up To Cancer Dream Team Translational Research Grant must be submitted by **Tuesday**, **January 16**, **2018**. See page 11 for further Application Instructions.

RESEARCH PROJECT CRITERIA

The SU2C Dream Team Translational Cancer Research Grants 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 particular organ sites, patient populations (such as pediatrics) or on innovative methods of treatment. 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. 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.

Through a partnership with leading health care research and innovation collaborative OptumLabs, each team will have the ability to conduct research using OptumLabs' proprietary database of de-identified claims and electronic health record data, analytic tools, and research support to pursue the proposed goals of the Dream Team. Appendix A provides more information on OptumLabs. Collaboration with OptumLabs provides researchers access to real world data to support health service and population health research.

OptumLabs will be conducting information sessions for applicants who are interested in learning more about the OptumLabs Data Warehouse. If you would like more information or to register to attend, please email proposals.optumlabs@optum.com by August 1, 2017 and include your name, institution and Dream Team Leader name. OptumLabs will contact interested parties about next steps, including dates and times of the information sessions.

DREAM TEAM 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.

Definitions.

<u>Dream Team Leader (DTL)</u>. 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 AACR's Scientific Review and Grants Administration (SRGA) staff.

<u>Dream Team Co-leader</u>. 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 AACR's SRGA staff.

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

<u>Dream Team Project Manager.</u> 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

American Association for Cancer Research. The PM is responsible for the coordination of all team efforts to consistently maintain a high level of functionality, collaboration and communication.

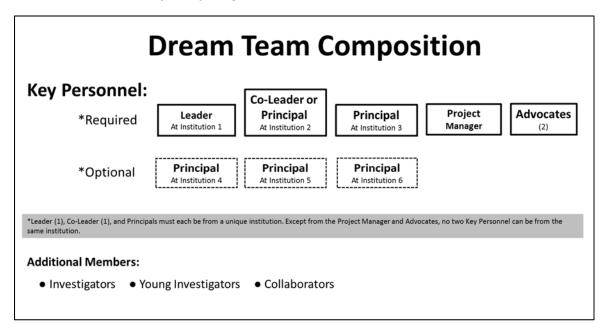
Advocates. Advocates bring the perspectives of those affected by cancer (e.g., patients, survivors, caregivers) to the work of Dream Team. They enable the Dream Team scientists to see their research through the eyes of the target audience and integrate these perspectives into the direction of the Dream Team research. While each Dream Team has unique needs, Advocates commonly suggest ways to minimize patient burdens in clinical trial protocols, develop patient-friendly consent forms, and reduce disparities in clinical trial participation by increasing awareness and using culturally appropriate materials and methods.

<u>Investigators</u>. 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.

<u>Young Investigators</u>. 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.

<u>Collaborators</u>. 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. No SU2C funds may be directed to a Collaborator.

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



The Dream Team Leader, Dream Team Co-leader, Dream Team Principals, Dream Team Project Manager, and Advocates are collectively referred to as <u>Key Personnel</u>. The Dream Team Leader, Co-leader and Principals, must have acquired a doctoral or medical degree, and must be independent investigators affiliated with an academic, medical, or research institution.

The Dream Team Leader and Co-leader are expected to each dedicate at least **20 percent (or 40 percent combined)** of their time and effort to the Dream Team research project. Dream Team Principals 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 Dream Team Leader, Co-leader, or Principal from any given institution at the time of their initial appointment on the Team. Except from the Project Manager and Advocates, no more than two Key Personnel may be from affiliated institutions. It is expected that additional Investigators from the Dream Team Leader's, Co-leader's or Principals' 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 Dream Team Leader, Coleader, or Principal, however their participation as Collaborators is encouraged, where appropriate, to foster the development of novel diagnostic and treatment strategies. No grant funds may be directly awarded to Collaborators or any other individual working within a U.S. government institution/agency or a for-profit industry. Confidentiality and intellectual property issues must be negotiated with Collaborators prior to their participation in a Dream Team research project.

Young Investigators, including junior faculty, postdoctoral fellows, clinical research fellows, or any other researchers working under the direction of a scientific mentor, 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.

There are no citizenship or residency status restrictions. Neither members of the SU2C SAC nor members of their individual laboratories are eligible for funding as part of the Stand Up To Cancer Dream Team Translational Research Grant. Key Personnel should not be funded on more than one SU2C-sponsored Dream Team grant. Except for the Dream Team Leader and Co-leader, 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 AACR SRGA Office at su2c@aacr.org prior to submitting the proposal.

EVALUATION OF PROPOSALS

The SAC will review the proposals for the Stand Up To 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 Advocates.

The SAC 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 this cancer type(s);
- Novelty of the hypothesis or methodology;
- Degree to which the studies will have a positive clinical impact on the prevention, detection, or treatment of 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 the AACR is required.

Contracts. A Grant Agreement will be executed between the AACR 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 must agree to commence the Dream Team research project described in the proposal on or about the time the first grant payment is received by the Lead Institution. If the Dream Team Leader is unable to commence the Dream Team research project at that time, the AACR SRGA Office should be immediately notified. The AACR 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 3-year term. A detailed budget for the overall Dream Team project will be required, along with separate budgets for expenses related to the research components conducted by each of the Dream Team Leader, Co-leader, and Principals. Budget expenses must be justified. Dream Teams are asked to allocate funding to the three years according to realistic expectations (e.g. the budget for the first year should be smaller than other years to account for time required for start up of the projects, regulatory approvals, etc.). All funding is contingent upon milestones and objectives being appropriately selected and satisfactorily pursued and achieved, as determined by the AACR and the SAC.

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 on the Dream Team (i.e., Leaders, Principals, and/or Senior Investigators within each of the collaborating institutions);
- 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 SAC, 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.

Payments. The Dream Team Leader and the 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. Quarterly installment payments will initiate within three months after the Grant Agreement has been signed and no earlier than the start date agreed upon by the Dream Team Leader and AACR SRGA Office. Assurances that all contractual agreements have been negotiated and signed, as well as organizational assurances/certifications, will be required prior to receiving payments. The Dream Team Leader and the Institution acknowledge and accept that subsequent funding is contingent upon the timely submission of progress and financial reports that are reviewed and found to be satisfactory by the AACR and the SAC.

Reporting Requirements. The semi-annual Progress Reports are a tool to ensure that the Dream Team is meeting its pre-defined Milestones and Deliverables, and is on track for achieving the ambitious goals that this grant requires. Progress reports are to be submitted twice a year (June 15 and December 15) and are intended to highlight the accomplishments of that specific time period. Progress Reports will be reviewed by AACR, SU2C, and a Review Team drawn from the SAC.

AACR may withhold release of any future Grant Funds until the reports have been filed and approved. All funding is contingent upon Milestones and Deliverables being satisfactorily pursued and achieved, as determined by the SAC, AACR, and SU2C. If the accomplishments have not met the standards of the SAC, the Committee will provide detailed information on specific areas of deficiency and its recommendations. All deficiencies will need to be addressed by the Dream Team. 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. These meetings will include all key personnel involved in the Dream Team project as well as staff from the AACR SRGA Office as necessary. In addition, Dream Team Leaders are required to meet with the SAC and all other Team members twice a year, following the submission of Progress Reports, to thoroughly discuss the Teams' progress. One of these meetings will take place at the annual SU2C Scientific Summit held in late January. These events will provide opportunities for Dream Team Leaders to engage in integrated team collaboration. Dream Team Leaders may also be requested to meet individually with the SAC.

A final written progress and financial report shall be submitted no later than sixty (60) days after the ending date of the grant term. Detailed instructions on completion of a satisfactory progress and financial report will be provided by the AACR SRGA Office prior to the report due date.

The AACR, 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 an AACR or 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 be cited as follows: "Research supported by a Stand Up To Cancer (SU2C) Dream Team Translational Research Grant (Grant Number: SU2C-AACR-DTXX-XX). SU2C is a program of the Entertainment Industry Foundation. Research grants are administered by the American Association for Cancer Research, the Scientific Partner of SU2C." In addition, whether during the term of the grant or afterwards, the Dream Team Members shall include this citation on any publicity or communications (external or internal) resulting from the grant, including but not limited to press releases, media reports, interviews, conference talks, and poster presentations of data. Copies of such publications must be forwarded to the AACR SRGA Office after acceptance, but before publication.

Intellectual Property. The Dream Team Leader and Lead Institution shall notify the AACR SRGA Office of any discovery that is or may be patentable or otherwise protectable under applicable law and that is discovered in the course of the research funded through this grant. The Dream Team Leader and Lead Institution shall be responsible for obtaining patent or other legal protection for each Invention that the Dream Team Leader or the Lead Institutions believes to have commercial potential, and for paying all costs associated with obtaining such protection. They are solely responsible for all commercial

exploitation of any Invention, and the AACR and SU2C, will have no responsibility therefor. Confidentiality and intellectual property issues must be negotiated with Collaborators prior to their participation in the research project. The Dream Team Leader and the Lead Institution shall notify the AACR SRGA Office 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 the AACR or SU2C and shall provide appropriate waivers of subrogation against the AACR 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 the AACR SRGA Office 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. The AACR 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/AACR 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 the AACR, and funds for human subjects research will NOT be released unless and until proof of all IRB certifications is received by the AACR. 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 as the funding agency, the AACR as the Scientific Partner of SU2C, 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

GETTING STARTED IN proposalCENTRAL

<u>If you are a new user of proposalCENTRAL</u>, follow the "**REGISTER**" link and complete the registration process. After you register, complete your Professional Profile (green tab, second from the left) before starting an application.

If you are already registered with proposalCENTRAL, access the site and log in with your Username and Password. If you have forgotten your password, click on the "Forgot your password?" link. Supply your User ID or e-mail address in the space provided; your password will be sent to you by e-mail.

<u>To start an application</u>, select the "Grant Opportunities" tab (gray tab furthest to the right). A list of applications will be displayed. Find the "SU2C Dream Team Translational Research Grant" and click the "Apply Now" link (second to last column) to create your application.

<u>To access your application</u>, select the "Manage Proposals" tab (blue tab first on the left). Below the "Manage Proposals" tab are several links; select the "In Progress" link. A list of all applications for which you have applied through proposalCENTRAL will appear. Find the program titled, "SU2C Dream Team Translational Research Grant". Then in the "Edit" column (second column from the left), select the "Edit" link to access your application.

Complete all fields in the application and all templates that are provided. Upload all requested documents in portable document format (PDF). See the proposalCENTRAL FAQ section, https://proposalcentral.altum.com/FAQ/FrequentlyAskedQuestions.asp, for more information.

If you have any difficulties registering, logging in, or creating your application, contact proposalCENTRAL Customer Support immediately:

LETTER OF INTENT SUBMISSION INSTRUCTIONS

A Letter of Intent (LOI) must be submitted by **12:00 p.m. (noon) U.S. Eastern Time on Tuesday, September 5, 2017** using the proposalCENTRAL website at https://proposalcentral.altum.com. An e-mail will be sent to confirm your online submission.

The LOI must not exceed two (2) pages and utilize no smaller than 11-point Times New Roman for the text, and no smaller than 9 point type for any figures, legends, or tables. The following components are required:

- <u>Title of Research Project</u> Should not exceed 75 characters, including spaces. Do not use abbreviations unless absolutely necessary.
- <u>Project Summary Statement</u> Briefly describe the idea for a translational research project and provide justification for the proposed research project with background information. After submitting the Summary Statement in proposalCENTRAL, please select the <u>Research Area(s)</u> and <u>Tumor Site(s)</u> most appropriate to the proposed project.

- <u>Clinical Impact</u> Describe how your proposed research as a multidisciplinary, multi-institutional Dream Team would result in rapid advancement in the treatment cancer and deliver near-term patient benefit.
- <u>Projected timeline</u> toward realizing the clinical impact.
- Approach Describe the research approaches and identify Key Personnel, i.e. Dream Team Leader, Co-leader, and Principals, whose expertise would contribute successfully to the suggested research project. Each Team will consist of a Dream Team Leader (DTL), a Dream Team Co-leader, no more than four Dream Team Principals (DTP), a Dream Team Project Manager and at least two Advocates. Dream Team Leader, Co-leader, and Principals must be from different institutions (with a maximum of 6 institutions).

Additional information:

- References references to publications supporting the proposed research project may be included (does not count toward the 2-page limit).
- <u>Biosketch</u> Upload NIH Biosketches for the Dream Team Leader, Co-leader, and Principal(s). Do not exceed five (5) pages per individual. The NIH Biosketch template is available for download at http://grants.nih.gov/grants/funding/424/SF424R-R biosketchsample VerC.docx.

FULL PROPOSAL SUBMISSION INSTRUCTIONS

Invited, full proposals must be submitted by **12:00 p.m.** (noon) U.S. Eastern Time on Tuesday, January **16, 2018**, using the proposalCENTRAL website at https://proposalcentral.altum.com. An e-mail will be sent to confirm your online submission.

The required materials to be submitted, in the order listed and using the templates provided where applicable, are as follows:

- Signature Pages, with contact information and the original signatures of the Dream Team Leader, Co-leader, Principals, Advocates, and Institutional Signing Officials. *Signatures must be in blue ink and submitted in color.
- Lay Abstract
- Research Project Proposal
- Budget
- Budget Justification
- NIH Biosketch of Dream Team Leader, Co-Leader, and Principals (no template is provided)
- Letters from Investigators and Collaborators
- Project Milestones
- Appendices, if applicable

The following information is required to submit a complete application. Numbers correspond to the application sections found on the left side of the proposalCENTRAL website.

- **1. TITLE PAGE.** Your title has been brought forward from the approved Letter Of Intent (LOI). Do not make any changes to the title or your application may be disqualified from funding consideration.
- **2. DOWNLOAD TEMPLATES & INSTRUCTIONS.** The Program Guidelines, and Full Application Instructions, and all templates can be downloaded from this page. You must download the following

documents: Signature Pages Template, Lay Abstract Template, Research Project Proposal Template, Budget Template, Budget Justification Template, and the Project Milestones Template to your computer.

- Click the 'Download' link to save templates to your computer.
- Complete the templates and convert it to PDF format. You do not need to be connected to the internet or proposalCENTRAL while working on the templates.
- Upload the completed template files to your online application in the section for attaching files.

See page 16 for instructions on how to upload completed template or your complete application.

- 3. ENABLE OTHER USERS TO ACCESS THIS PROPOSAL. Optional.
- **4. DREAM TEAM LEADER.** Dream Team Leader information has been brought forward from the approved LOI. Ensure that all fields are accurate.
- **5. INSTITUTION & CONTACTS.** Institution and Contacts have been brought forward from the approved LOI. Ensure that all fields are accurate.
- **6. KEY PERSONNEL (DREAM TEAM MEMBERS):** Key Personnel have been brought forward from the approved LOI. Enter Key Personnel (Leader, Co-leader, Principals, Project Manager, and Advocates) as well as any other Dream Team members. Definitions of Dream Team Members are provided on page 3.
- 7. ORGANIZATIONAL ASSURANCES. The assurances/certifications are made and verified by the signature of the Institutional official signing the application. The AACR does not require the supporting letters with your application. However, if awarded, IRB and/or IACUC approval (if applicable) must be submitted in writing to the AACR SRGA Office.
- **8. UPLOAD ATTACHMENTS.** Prepare and upload the following documents into your application in portable document format (PDF). Details are provided below.
 - I. Signature Pages and Contact Information
 - *All signatures must be in blue ink and submitted in color electronically.
 - A. <u>Title of Research Project.</u> The title should not exceed 75 characters in length (including spaces). Do not use abbreviations unless absolutely necessary.
 - B. <u>Dream Team Leader (DTL)</u>. 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 AACR's SRGA staff.
 - C. <u>Dream Team Co-leader</u>. A Dream Team Co-leader should be designated by the Dream Team Leader to assist in directing the scientific and technical work of the Team. A Co-leader will assist in directing the scientific and technical work of the Team and will serve as an alternate contact person for AACR's SRGA staff.

- D. <u>Lead Institution</u>. The Lead Institution is the organization at which the Dream Team Leader is employed, and it will be legally and financially responsible for the conduct of activities supported by the grant.
- E. <u>Co-leader's Institution.</u> Provide the name and mailing address for the organization at which the Dream Team Co-leader is employed.
- F. <u>Administrative Official at Lead Institution.</u> Provide the name of and contact information for the Lead Institution administrative official to be notified if an award is made.
- G. <u>Official Signing for Lead Institution.</u> Provide the name of and contact information for the official signing for the Lead Institution.
- H. Lead Institution Certification. In signing the application, the Authorized Lead Institution Representative certifies that the Lead Institution will comply with all applicable policies, assurances and/or certifications referenced in the application. The Lead Institution is responsible for the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the application. The signer further certifies that the Lead Institution will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from this application. The Lead Institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

<u>NOTE:</u> It is recommended that the collaborating Institutions be provided with the program guidelines as soon as possible. Certification of the Dream Team application by the Co-leader's, and each of the Dream Team Principal's Institutions (i.e., signatures from the Institutions' Representatives) will be required at grant submission.

- I. <u>Dream Team Principal(s) and Advocates</u>. Do not enter information for Investigators, Collaborators, or fellows or research assistants.
- J. <u>Dream Team Member Certification.</u> Original signatures, in blue ink, of the Dream Team Leader(s), Principals and Advocates are required.
- K. <u>Dream Team Co-leader's and Principals' Institutions Certification</u>. In signing the application, the Authorized Dream Team Co-leader or Principal Institutional Representative certifies that the Institution will comply with all applicable policies, assurances and/or certifications referenced in the application. The Institution is responsible for the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the application. The signer further certifies that the Institution will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from this application.
- **II.** Lay Abstract of Research Proposal. This abstract, limited to 3,000 characters, 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. A scientific abstract must be included within the research project proposal.
- **III. Research Project Proposal**. Applicants must adhere to the following formatting guidelines in completing this section.

- Must use 12 point Times New Roman 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."
- Suggested tips and techniques for images in documents:
 - Reduce the file size of documents with images by "inserting" the image (as opposed to "cutting" and "pasting"). Save graphical images as JPEG or GIF files.
 Insert the image into the document by selecting "Insert Picture From File" from the MS Word menu.
 - o Insert only GIF or JPEG graphic files as images in your Word document. Other graphical file formats are either very large or difficult to manipulate in the document.
 - o Do not insert Quick Time or TIFF objects into your document.
 - o Anchor the images that you embed in your document.
 - Once you have anchored the "inserted" image, you can format text to wrap around the image.
 - o Do not edit your images in Word. Use a graphics program.
 - o Do not embed your images in tables, text boxes, and other form elements.
 - O Do not add annotations over an image in Word. Add annotations to the image itself in a graphics program.

Present the required information, using the template, in this order:

- A. <u>Contents page.</u> Complete the Table of Contents by indicating the appropriate page numbers for each section; do not exceed one page.
- B. <u>Title of Research Project.</u> The title should not exceed 75 characters in length (including spaces). Do not use abbreviations unless absolutely necessary.
- C. <u>Scientific Abstract.</u> Limited to 3,000 characters (including spaces). Should provide a clear, concise description of the proposed work, including the background, objective or hypothesis and its supporting rationale; specific aims of the study; study design; and clinical impact and significance of the proposed work.
- D. <u>Proposal Narrative.</u> Limited to 20 pages, including figures and tables. References and appendices do not count against this page limit. Describe in-depth the proposed research project, including:
 - 1. Background and Rationale
 - 2. Specific Aims
 - 3. Research Design and Methods
 - 4. Projected Timeline and Milestones. Provide a sequence or timetable for the project and identify the milestones by which the success of the proposed research could be measured.

- 5. Significance and Therapeutic Impact on the prevention, detection, or treatment of cancer. If the specific aims are achieved, state how clinical practice will be advanced.
- E. <u>Collaboration/Dream Team Members</u>. Limited to six (6) pages. Include a narrative describing the value-added activities of the team/unique benefits afforded by the collaboration and the plan for coordinating the research across the multiple performance sites. List all members of the Team, including: Dream Team Leader, Co-leader, Principals, Project Manager, Advocates, Investigators, Collaborators, fellows, research assistants, and support staff. Provide professional titles and affiliations and a description of each member's substantive and quantifiable contribution to the research project.
- F. <u>Facilities</u>. Limited to three (3) pages. Please provide a description of the research facilities, equipment and other resources available for this project. For clinical trials, please list participating sites.
- G. <u>References.</u> List all relevant publications cited in the proposal narrative.
- H. Other Support. Provide details of any current funding or funding applications in progress to support any component/subproject of the proposed Dream Team research project.
- IV. Budget. Dream Teams may apply for total support of up to \$10 million over a three year term. Provide budgets for the overall Dream Team project, as well as separate budgets for expenses related to the research components/subprojects conducted by each Dream Team Leader, Coleader and Principal. Indicate expenses directly attributable to the proposed research. For clinical trials, patient recruitment cost must be included in the Dream Team Budget (under "Other Expenses" in the Budget Excel document). To aid in patient recruitment to clinical trials, a

"Other Expenses" in the Budget Excel document). To aid in patient recruitment to clinical trials, a Dream Team web page and short Dream Team video will be provided to the Team on the SU2C website. SU2C has other fee-based production resources that can be used to develop recruitment tools prior to proposal submission or after award. If desired, a representative of the Dream Team should contact SU2C to discuss needs for patient recruitment.

Dream Teams are asked to allocate funding to the three years according to realistic expectations (e.g. the budget for the first year should be smaller than other years to account for time required for start up of the projects, regulatory approvals etc.). See "Grant Terms, Use of Funds" on page 7 for further details.

- V. 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 Dream Team Leader, Co-leader, and each Principal is required for all items of 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.
- VI. Biosketch of the Dream Team Leader, Co-leader and Principals. Upload NIH Biosketches for the Dream Team Leader, Co-leader, and Principal(s). Do not exceed five (5) pages per individual. No template is provided (the NIH biosketch template is available for download at http://grants.nih.gov/grants/funding/424/SF424R-R biosketchsample VerC.docx).

- VII. Organizational Assurances. The assurances/certifications are made and verified by the signature of the Institutional Official signing the application. Signatures from official representatives of each of the Dream Team Leader, Co-leader, and Principal's Institutions certifying the Dream Team application will be required at time of submission. It is the responsibility of the Dream Team Leader and Institution to ensure that organizational assurances/certifications from all Dream Team Member Institutions are obtained. Proof of organizational assurances/certifications from all collaborating Institutions must be received before payments will be released. In addition, letters of endorsement from the Dean, Department Head, or Director of all institutions represented by the Team members, certifying contents of application package, written in English, will be required prior to payment.
- VIII. Letters from Investigators and Collaborators. Submitted letters should confirm the scope of the Investigators' and Collaborators' involvement in the proposed research. Submitted letters should be on institutional or organizational letterhead.
- **IX. Project Milestones.** The milestones will be used to define a timeline for the research activities that you propose to accomplish over the duration of your project. Reporting progress towards milestones will be incorporated into the semi-annual reporting requirements for the project if funded.
- **X. Appendices.** Additional documents such as clinical trial preliminary data or summaries of clinical trial protocols may be included as an appendix. Figures, tables, and other references to information contained within the Proposal Narrative are not allowed. The appendix may not be used to circumvent the 20-page limit for the Proposal Narrative. Publications are not allowed. References to publications must be made in the Proposal Narrative.

Uploading the attachments into your application

Once you have converted your attachment to PDF files, the next step is to upload the files to your online application:

- Make certain that the converted PDF files are closed on your computer;
- Open your application and go to the section for attaching files;
- Enter your own description of the file in the "Describe Attachment" field;
- Select the appropriate type of attachment from the drop-down list. NOTE: After selecting
 attachment type, the screen will show the allowable file types (e.g., PDF, .doc) that are allowed
 for that type of attachment;
- Click on the "Browse" button to select the file from your computer;
 - o A 'choose file' dialog box opens for you to search for the template file on your computer's hard disk or local area network.
 - o Select the file and click "Open."
 - o The file location and name will display in the window adjacent to the Browse button.
- Click on the "Upload Attachment" button. You will get a confirmation message on your screen
 that the file was uploaded successfully. You will also see that your file is now listed in the
 Uploaded Attachment section of the screen. Two links are available in each row of an
 uploaded attachment: DEL and SHOW. "Del" allows you to delete the file, if necessary, and
 "Show" opens the uploaded file. It is strongly recommended that you open and review your
 uploaded file.

If, for any reason, you wish to modify the attached file, make the revisions to your *original* file on your computer (off-line), convert the file to PDF and use the same process above to attach the newly revised file. **Delete any previously submitted versions of the file before submitting your application.**

Submitting Complete Application

- 1. PI DATA SHEET. This is an automatically populated data sheet based on applicant's proposalCENTRAL profile. Information for gender, race, and ethnicity must be provided to the AACR. If fields are not populated, go to Section 4, Applicant, and select the "Edit Professional Profile" tab in the center of the screen. The Applicant must then go to the column on the left hand side of the screen, select "4) Personal Data for Application," and enter his or her race, gender, and ethnicity. This information is for demographic purposes only. The Joint Scientific Advisory Committee does not receive this information.
- 2. VALIDATE. Validate the application on proposalCENTRAL. This is an essential step. An application that has not been validated cannot be submitted. 'Validate' checks for required data and required attachments. You will not be able to submit if all the required data and attachments have not been provided.
- **3. SUBMIT.** After the application has been validated the application must be submitted. The submit button will only appear after the document has been validated. Click the "SUBMIT" button. A confirmation email will be sent by proposalCENTRAL to confirm that the application was submitted. If you do not receive an email confirming the submission of your application, please contact proposalCENTRAL immediately.
- **4. SIGNATURE PAGE(S) AND PRINT APPLICATION.** After successfully passing the validate check you are ready to print the signature pages and the attached PDF files. Use the second print button "Print Attached PDF Files." Click this button to print the attached PDF files. Ensure that all documents are correct and complete.

IMPORTANT: A confirmation email will be sent once the proposal is submitted. If you do not receive this email and believe that you have submitted your proposal you should immediately contact proposalCENTRAL. It is the <u>responsibility of the applicant</u> to ensure the application was completed correctly, all required information is present, and that the proposal was officially submitted through proposalCENTRAL.

CHANGES TO THE APPLICATION

Withdrawal of application: The Dream Team Leader should advise the AACR SRGA Office promptly, in writing, should he/she decide to withdraw the application for any reason. The letter (or e-mail) should include the DTL's name, the title of the proposal, and the reason for withdrawal.

Change of address: Notify the AACR SRGA Office in writing of any changes of address, e-mail or phone number for any Dream Team Member, following the submission of an application. Include your name and the proposal title.

Change of institution: If any Dream Team member changes institution, the Dream Team Leader should contact the AACR SRGA Office to determine whether your application can be reviewed.

INQUIRIES

Inquiries about the program guidelines, eligibility requirements, and application materials can be directed to the AACR SRGA Office at:

United States

E-mail: <u>su2c@aacr.org</u> Phone: +1-215-446-7242

APPENDIX A

OptumLabs™ is an open, collaborative research and innovation center founded in 2013 by a partnership between Optum and Mayo Clinic, and dedicated to improving patient care and patient value. Our goal is to accelerate high-impact scientific discovery through data-driven health care research, leading-edge data science and the power of collaboration.

Together with our partners, OptumLabs leverages a unique combination of data, analytics and expertise to drive our program of research and innovation. OptumLabs' core linked data assets in the OptumLabs Data Warehouse (OLDW) include de-identified claims data for privately insured and Medicare Advantage enrollees, de-identified electronic medical record (EMR) data from a nationwide network of provider groups, and a de-identified database of consumer lifestyle information. The database contains longitudinal health information on more than 160 million individuals, representing a diverse mixture of ages, ethnicities and geographical regions across the United States. The EMR data contains health information that is sourced from provider groups and reflects all payers, including uninsured patients. This information contains various types of clinical observations, procedures and diagnosis codes and information derived from Natural Language Processing (NLP) for added clinical richness on family history, medication changes, and reported signs, diseases, and symptoms.

At OptumLabs, our 25+ partners bring expertise and different viewpoints from across the health care ecosystem to shared challenges in care, facilitating innovation and discovery. From academia to hospital networks to life sciences companies, consumer organizations, members of the government and more, researchers have access to thought-leading voices from every part of the health system.

OptumLabs will be conducting information sessions for applicants who are interested in learning more about the OptumLabs Data Warehouse. If you would like more information or to register to attend, please email proposals.optumlabs@optum.com by August 1, 2017 and include your name, institution and Dream Team Leader name. OptumLabs will contact interested parties about next steps, including dates and times of the information sessions.