

UNIVERSAL GRANT APPLICATION INFORMATION

GENERAL INFORMATION

The Cure Starts Now Foundation (CSN) is an IRS 501C non-profit charity dedicated to educating, aiding and funding the search for a cure for brainstem glioma and other forms of pediatric brain cancer in the hopes of curing all cancers.

The Foundation seeks to fund research investigating cures for pediatric brain cancers with a focus on Diffuse Intrinsic Brainstem Glioma (DIPG). Our focus is to support translational and clinical research projects in those areas.

GRANT PROGRAM

Applicants may request funding up to \$100,000 for one year. Grants may be renewed for one year at the request of the investigator and at the recommendation of the Medical Advisory Council Chair. Grants in excess of \$100,000 may be conditionally reviewed and approved with the approval of the Medical Advisory Council chair, provided all other requirements are followed. Current members of the DIPG Registry, as defined below, may apply for an increased grant funding of \$200,000 for one year (note special requirements listed in section 4 below).

Criteria for Participation in Registry and Subsequent Access to Collaborative

Funds: (Pertains to investigators and the institutions they represent.

- 1. Institutional Approval (e.g. Non-human subjects research determination and HIPAA waiver granted/IRB approval)
- 2. Data submission (i.e. deceased pt. records yr.2000-present)
 - a. Includes clinical records, imaging and tissue (if available) for central review and digitization
 - b. 50% submitted within 6 months of institutional approval
 - c. 100% submitted within 1 year of institutional approval
 - d. Distributing Registry recruitment material (e.g. brochures) in clinic to DIPG patients and families.
- 3. Institutions who submit data would be able to publish their own cohort within one year of submission. Thereafter, they can publish their cohorts at any time; however, the Registry reserves the right to include those cohorts as part of its cohort for publishing.
- 4. If an institution waives the one-year limit (#3 above), they are eligible to request funding for a grant up to \$200,000 (standard limit is \$100,000)

Approved grants are expected to be implemented within 6-months of acceptance and no grant shall be contingent on other external funding unless explicitly approved in writing by the Chairman of the Medical Advisory Council of The Cure Starts Now. It is the purpose of The Cure Starts Now to avoid a duplication of funding for the same work across all foundations due to a limitation of resources. To that end, any solicitation of foundation, industry or other third party funds aimed to complete the study goals after CSN funding has been approved for such study goals will result in a review by the CSN, and such third party funding solicitation may result in a revocation of grant proceeds unless such action is approved in advance by the Chairman of the Medical Advisory Council of The Cure Starts Now. Considerations will be made for multiple grant solicitations that represent separate expense line items or an expansion of an existing research project with the prior approval of the Chairman of the Medical Advisory Council of The Cure Starts Now.

Funding is for direct costs related to the research project. Examples of direct costs include personnel, salary, supplies, equipment and patient care expenses. Support for salary must not exceed percentage of effort related to the research. Institutional costs may be considered, but it is recommended that justification be provided in the budget of the grant. A total of 10% or less of institutional and indirect costs is recommended. Travel costs are excluded from funding in this grant application, but investigators may request additional support from The Cure Starts Now to travel to meetings to present research funded by the Foundation. These requests will be considered on a case-by-case basis.

Additional allocated funds are available as part of the DIPG Collaborative program administered by The Cure Starts Now. Although it is not a requirement to file a duplicate application and the Medical Advisory Council will automatically select the appropriate category based on the answers supplied, applicants for DIPG.com Symposium grants are strongly encouraged to detail a multi-institutional collaboration in their answer to Section 5.a.

GRANT PROCESS

Grant applications will be accepted for one funding cycle each year. The deadline for receipt of the application is June 1. Electronically uploaded submissions (see Application Requirements) with all attachments by June 1 with a formal grant received via mail by June 5th will be deemed in compliance. Incomplete applications will not be considered. At the discretion of the Medical Advisory Council Chairman and based upon research needs, special grant cycles may be considered outside of June 1.

Applications will be reviewed and final determination on funding will be made within three months with funding to begin immediately. If internal review has not yet been performed or the study cannot begin within 6-months of grant approval, funds will be withheld until such time that The Cure Starts Now Foundation is notified that the program has been formally approved and will be implemented. If program approval is not received with 6 months and the program is not implemented, it shall be the sole discretion of the Medical Advisory Council Chairman to either deny, modify or delay grant funding to the institution. Grant applications will be judged on a peer-reviewed basis. The steps in the grant determination process are:

- The Medical Advisory Council for The Cure Starts Now Foundation will initially review the applications for merit based on criteria listed below.
- When necessary, grant applications will be sent to physicians or investigators in the particular field of interest for an intensive review of the scientific merit.
- The Medical Advisory Council will then take the peer review assessment of scientific merit and make further assessments of the grant's adherence to additional criteria listed below. The Medical Advisory Council will then rank the applications and make recommendations to the Board and the Strategic Advisory Council. The Board will make final determinations regarding funding of grant applications. All decisions by the Board are considered final.

A progress report must be submitted by the investigator(s) on annual intervals and at the end of the funding period. Failure to submit a progress report will exclude the investigator from any future funding from the foundation. Additionally, upon approval of funding by The Cure Starts Now, the institution receiving funding must supply a letter acknowledging the grant and amount as well as a link to their website containing further information about the study for the education and coordination of affected individuals and families. A link to this website as well as the answers submitted in Section 1 and Section 2 submitted by the investigator will be posted on The Cure Starts Now website.

Funding by The Cure Starts Now, and all participating foundations must be specifically acknowledged in all presentations and publications that involve research funded by the foundation. Our goal is to share research and information, so it is mandatory that any and all study results will be shared promptly with the scientific community and not be kept strictly for proprietary purposes. Failure to promptly and fully share any and all study results with the DIPG and broader scientific community may result in a pause and/or complete discontinuation of any funding yet to be disbursed under such research funded by the foundation. Consideration for a limited delay, not to exceed 30 days, in reporting of results will be given to unpublished data that is the subject of a patent application. For clarity, any and all data that is included in a filed patent application must be made available immediately following the filing of such a patent application.

Submissions to The Cure Starts Now Foundation for grant approval should not be construed to be confidential information and the submitting organization agrees to release The Cure Starts Now Foundation from any and all liability from the discussion, Internet posting or consideration of all documents submitted. If requested in writing by the applicant, posting of application answers to section 1 and 2 will only be posted for public view at www.thecurestartsnow.org, or www.dipg.org and associated sites. All other responses and submissions will still be shared with members of the Medical Advisory Council and partnering foundations.

GRANT ELIGIBILITY AND CRITERIA

Applicant Eligibility:

- Must be an MD, DO, PhD, DrPH or equivalent
- Must be a member of a non-profit organization or a valid medical/scientific organization.
- Must be up to date with any previous funding through The Cure Starts Now, which includes progress report submissions.

Grant applications will be assessed based on the following criteria:

- Scientific merit
 - What is the hypothesis and does the study adequately answer and address the hypothesis? Does the study use valid research and statistical methods?
- Disease impact
 - Does the study propose an intervention or clinical tool that will reduce the morbidity or mortality from or potentially find a cure for pediatric brain cancer?
- Innovation
 - Does the research study propose a novel approach or represent advancement in current treatment of pediatric brain cancer?
- Feasibility
 - Is the study likely to meet its goals during the funding period? Can the research findings be translated into clinic practice? Are the research findings likely to result in a direct change in morbidity or mortality of pediatric brain cancer in the near future?
- Expertise of investigator(s)
 - Do the investigators have the expertise to meet their research goals?

The Medical Advisory Council and its members utilize a modified NIH scoring system to evaluate and score each grant application. Members score each study on a 1-9 scale for each of the criteria listed above (1 being considered as meeting qualifications and 9 considered deficient). In addition, they provide an overall Priority Score that is used for ranking each of the studies. An average of the Priority Scores for each of the studies is calculated, and then the average scores are ranked highest to lowest. The Council will then make recommendations to the Board and Strategic Advisory Council based on these scores.

APPLICATION REQUIREMENTS

Applications should be single spaced and 12-point font. Margins should be not less than 0.5 inches on all sides. Page size is 8.5 x 11 inches. These guidelines are to ensure readability for our reviewers. One copy with original signatures and proposal along with

a flash drive with the application in PDF format and proposal should be submitted to the foundation.

Completed application materials should be sent to:

Dr. Gavin Baumgardner Chairman, Medical Advisory Council The Cure Starts Now Foundation 10280 Chester Road Cincinnati, Ohio 45215

In lieu of a flash drive, submissions may also be electronically emailed to the below location, however, they must be accompanied by June 5th by a physical application to the above address. Electronic submissions should be sent to:

grants@thecurestartsnow.org

Please use the word "Grant" in the subject header for proper routing. Electronic submissions by PDF only please and as one complete file. We are unable to ensure that multiple files sent or multiple revisions will be properly routed so please verify before sending.

If sending a larger file, you may also use a dropbox link found at <u>www.thecurestartsnow.org</u> in the grants selection. We are not able to utilize any other dropbox link or upload system other than the one provided on our website for applications.

In rare occasions The Cure Starts Now Foundation Medical Advisory Council may consider applications for programs that have also been filed with other organizations. This is done in an effort to limit paperwork in the hopes of advancing medical research resources. Typically, this will only be approved for detailed and complex applications and only in combination with a cover letter detailing the application submittal to The Cure Starts Now. In all cases, formal written approval must be obtained in advance from the Chairman of the Medical Advisory Council to accept such a submission. Submissions sent without advance approval will be excluded from consideration. For approval or questions regarding the application process, grants@thecurestartsnow.org.

APPLICATION OUTLINE REQUIREMENTS

All applications must include the Main Principal Investigator, Institution and request amount in the footer of each page. Pages must also be numbered.

- 1. Section 1: Contact Information
 - a. Primary Investigator
 - i. Name and title
 - ii. Address
 - iii. Phone number (s)
 - iv. Email address
 - v. P.I. must include original signature below this contact information.
 - b. Individual with institutional authority to sign on behalf of the institution. This includes signing financial reports and receiving checks from The Cure
 - Starts Now Foundation.
 - i. Name and title
 - ii. Address (for correspondence and for sending checks)
 - iii. Phone number(s)
 - iv. Email address
 - v. This individual must include original signature below this contact information.
- 2. Section 2: Executive Summary
 - a. This is a summary of the hypothesis, goals, background, clinical significance, design and methods of the proposed study. <u>The summary is not to exceed one page</u>. This summary will aid our reviewers in determining if the study generally meets our five criteria for funding outlined in the General Grant Information section. These criteria include:
 - i. Scientific Merit
 - ii. Disease Impact
 - iii. Innovation
 - iv. Feasibility
 - v. Expertise
 - vi. Total Grant Amount Requested
- 3. Section 3: Copy of This Grant Application
 - a. This is a copy of the entire 7-page application, with the Primary Investigator signature at the bottom of each page and the final acceptance signature at the end of the document, indicating compliance with the terms of the CSN grant process and regulations.
- 4. Section 4: Description of Research Proposal
 - a. This is a detailed description of the research project. This section <u>should</u> <u>not exceed 10 pages in length</u>. Details that must be included in this section and must be listed in the following order:
 - i. Hypothesis proposed and anticipated results
 - ii. Specific aims

- iii. Background and rationale for the proposed research project
- iv. Research design
 - 1. Includes details about the design of the project, including plan for statistical analysis. Describe techniques or modalities in sufficient detail that reviewers can make a reasonable determination of feasibility.
- v. Use of human or animal subjects
 - Describe the detailed plan for how human subjects will be recruited for the study or how study samples will be collected. If animals are involved, describe plan for their use in the project. Also include if IRB approval has been obtained for this project with a reference to contact for verification or letter of approval.
- vi. Disease Impact and Innovation
 - In layperson's terms, describe how results from this research project would lead to a potential decrease in mortality or morbidity or potential cure for pediatric brain cancers. Also, in this section, please explain how the research proposal is a novel approach to pediatric brain cancers.
- vii. References
- 5. Section 5: Budget
 - a. This section should be <u>no more than one page in length</u> and should include budget information and justification. All amounts should be listed in US Dollars. The following categories must be included:
 - i. Personnel costs
 - ii. Salaries and wages
 - iii. Fringe benefits
 - iv. Supplies
 - v. Equipment
 - vi. Patient care costs
 - vii. Other expenses (descriptive line item list)
- 6. Section 6: Collaborations and Conflicts of Interest
 - a. Include biographical information for any investigators, co-investigators and any known key personnel that will be working on the research project. If the study will be a collaborative effort between investigators, this should be outlined above and the co-investigator should include his or her information in Section 1, along with a designated official from their institution. Biographical information should be in NIH biosketch format. The biosketch should include a description of any other studies for which the investigator(s) is currently being funded or is involved with.
 - b. P.I. must include a statement in this section that discloses any potential conflicts of interest regarding the research project or its funding by The Cure Starts Now. The P.I. must sign this conflict of interest statement (no

stamps accepted). A potential conflict of interest is a situation in which a reviewer or individual involved in a funding decision, a family member, a friend, or other associate is in a position to gain or lose personally or professionally by the foundation's funding of the program.

- 7. Section 7: Regulatory Financial Compliance
 - a. Include a copy of a completed W-9 (included in the grant application paperwork). W-9 forms are only applicable for US grant applicants.

I have read and in consideration of any grant awarded for the research applied, agree to comply with the terms and requirements as stated above.

Signature

Date

Printed Name

Title