



Therapeutic Development Initiative

TDI Proposals for Funding Guidelines

Philosophy

Welcome to the Therapeutic Development Initiative (TDI), Solving Kids' Cancer's mechanism to support therapeutic development projects to improve survivorship for children with neuroblastoma and pediatric CNS tumors. SKC has a singular vision: To extend life for children with these forms of cancer today while making survivorship possible for all children by 2015. Here you will find important information about the TDI itself along with how to submit a proposal for funding.

PROPOSALS ARE ONLY ACCEPTED BETWEEN May 1 and June 30, 2010

THERAPEUTIC DEVELOPMENT INITIATIVE (TDI)

- The TDI encourages the use of the existing body of pre-clinical/clinical data that includes: new IND agents for other cancers; currently-approved agents for other cancers/indications; and investigator-initiated IND's for new agents. Solving Kids' Cancer then facilitates the rapid implementation of these findings into pilot studies; proof-of-concept projects and other novel clinical trials for children with the deadliest pediatric cancers.
- The TDI seeks to create new clinical applications of agents that are novel; non-redundant to currently existing clinical programs and have the potential to change the treatment paradigm.
- When a proposal is approved for support, the TDI and staff provide infrastructure that may include - contract negotiation, stewardship with industry, outside CRO function and external IRB review.
- The TDI is composed of an advisory board of scientists with diverse experience/expertise, many of whom are outside of pediatric oncology. This group makes recommendations for proposal funding, prioritization, as well as strategic consultation on the implementation of supported therapeutic development projects.

Submit a Proposal to the TDI

Overview

The TDI is accepting proposals for therapeutic development projects beginning **May 1, through June 30, 2010**.

Aligned with our vision, SKC values therapeutic development projects that positively impact children in treatment today as well as those newly diagnosed in the future. We seek proposals for clinical investigations in the form of **pilot studies, proof-of-concept projects** and other **novel clinical trials**. These should focus on therapeutic agents that are novel, non-redundant to current ongoing investigations and have the potential to change the treatment paradigm for neuroblastoma and/or pediatric CNS tumors.

Award Amounts and Timeline

Approved Proposals range in award amounts from \$50,000 to \$750,000. The supported project will have a life-cycle of no longer than two-years from the time the funding is received to completion of the project.

How to Apply

All proposals must be made electronically through Solving Kids' Cancer [TDI Online Portal](http://solvingkidscancer.org/work/submit-grant). <http://solvingkidscancer.org/work/submit-grant> The TDI Portal provides a simple and streamlined electronic proposal form emphasizing the high-level description of the proposal. The TDI format for proposal submission is called an **Idea of Intent**. The three required fields include:

- (1) The Proposal Title
- (2) The Proposal Summary - overview of the therapeutic idea (175-word maximum)
- (3) The Proposal Narrative – description of any pre-clinical data supporting a study in children, how the proposal is unique from other studies, and expected study goals and outcomes (1000-word maximum)

About the Idea of Intent Proposal

The spirit of an “Idea of Intent” request is to inspire the scientific research community to submit their best ideas for therapeutic development to improve survivorship for children with neuroblastoma and/or pediatric CNS tumors. We seek testable questions and ideas about therapies for these childhood cancers that may provide therapeutic solutions where currently there are none. Our goal is to fund “dream” ideas that are not currently being funded through existing sources.

Review and Approval Process

All applicants will be contacted before August 1, 2010 regarding the status of their proposal. At that time, applicants whose Idea of Intent proposals are reviewed as meeting the goals of the TDI may be requested to submit additional supportive materials related to the proposed project. (This follow-up request does not signify any type of approval). These may include budgets, NIH format biographical sketches, draft protocols, scientific references, timelines, milestones, and other elements.

A second review process will occur with the supportive materials. Secondary review does not constitute a pending approval. Final approval of a proposal will be based on assessment of feasibility and potentially continued communication with the applicant. Feasibility roadblocks may preclude a highly-rated proposal from being supported/developed. The goal of the TDI is to ultimately be a strategic partner with the investigator to streamline the process of developing clinical investigations.

More Information

Priority Criteria

Priority will be given to proposals that meet these key criteria:

- Hold the potential to impact and change the treatment paradigm
- Are novel and innovative.
- Have a high level of acceptance by parents and patients for timely accrual
- Are non-duplicative and strategic vis-à-vis the entire pool of clinical studies

Eligibility

- SKC welcomes applications from researchers within or outside the United States. Prior work in cancer research is not a prerequisite for applying
- Proposals submitted to the TDI must be made between May 1, 2010 and June 30, 2010. Other opportunities for submission of proposals for funding will be determined and announced once available.
- Research fellows applying for funding must identify a full-time institution faculty member with whom they are affiliated. Research fellows whose project is ultimately approved and funded will be expected to complete the proposed project

Applicable to All Proposals for Funding

- Application and required documents must be in English
- No institutional overhead or indirect funding will be provided under the terms of the grant
- All submissions are considered confidential and are available to the Scientific Advisory Board, the Board of Directors, and the staff of SKC only

Qualifications and Conditions

- All awards will be payable to grant recipients to administer for the purposes of the submitted grant only
- Submissions should request no more than 10% effort of Primary Investigators and Co-investigator expenses. Exceptions may be made for proposals documenting a need for more. Personnel costs may not exceed 10% of the total budget.

Any questions related to the May 1-June 30, 2010 proposal submission process should be addressed by email to: grants@solvingkidscancer.org

-OR-

Solving Kids' Cancer

ATTN: Grants

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