

# International Neuroblastoma Research Initiative 2018

Collaborative Funding Partners





*Advancing science; empowering parents; defeating neuroblastoma.*

# International Neuroblastoma Research Initiative 2018

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## 2018 Request for Applications

Letters of Intent Due Date: **7 September 2018**

### Two-Stage CHALLENGE GRANT

**Feasibility Grant Awards of \$35,000 for Sept 2018 – Jan 2019\***

**Final Project Grant Award circa. \$1,000,000 over 3 years (2019-2021)**

The CHALLENGE GRANT is to call for improvement in survival and quality of cure through an innovative pilot study for newly diagnosed high-risk neuroblastoma patients.

- **7 September 2018: Letters of Intent (LOI) due**
- **28 September 2018: Feasibility Grants awarded, with invitation to complete Full Proposal**
- **February 2019: Full Proposals due**
- **April 2019: Grant award announced**

*\* Limited additional funding potentially available at the discretion of Solving Kids' Cancer*

## About Solving Kids' Cancer

Solving Kids' Cancer in London and New York work together to support innovative clinical research into high-risk neuroblastoma and foster international collaboration within the research community.

### CONTACT

**Solving Kids' Cancer**

CAN Mezzanine, 49-51 East Road, London, N1 6AH

[www.solvingkidscancer.org.uk](http://www.solvingkidscancer.org.uk)

Research Coordinator: Leona Knox

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# Overview

## Project Description

This is a Request for Applications (RFA) to conduct a novel international pilot study for newly diagnosed high-risk neuroblastoma, seeking to improve survival outcomes with less toxicity using innovative therapeutic approaches.

- Proposals must include recruiting centres in the United Kingdom, Europe, and North America. The addition of recruiting centres outside these regions is not prohibited.
- This is a two-stage grant award process. Up to a maximum of 3 LOIs will be awarded Feasibility Grants to complete and submit Full Proposals.
- LOIs will be selected based upon novel and feasible approaches to improvements and reduced toxicity in all phases of treatment of high-risk neuroblastoma including induction, consolidation, residual disease, and maintenance.
- Proposals must be discussed with cooperative groups and evidence that there is a potential route through which a successful pilot study can be taken forward and incorporated into frontline clinical trial strategies.
- Full Proposals may include the use of biomarker-driven patient selection techniques to identify particular sub-groups who could benefit from new innovative therapeutic approaches.
- Full Proposals may further include rationale and planning for innovative approaches for children with a poor prognosis, pending a consensus being formed on prospective identification of such groups of patients.

## Budget

Feasibility Grants of \$35,000 will be awarded to winning LOIs to support development of Full Proposals. Expectations are that this grant will fund travel/meetings and may also be used for some small level of salary support (such as biostatistician), a comprehensive budget for which must be provided in the LOI. Limited *additional* funding is potentially available at the discretion of Solving Kids' Cancer, upon provision of a detailed breakdown of proposed expenditures and associated justification.

The final grant award will be over three years dispersed in milestone payments. Zero-cost extensions will be allowed, subject to approval by Solving Kids' Cancer. Funding is for direct costs only, with no overheads or indirects permitted. A detailed budget and justification for all trial costs will be required in the Full Proposal.

## Eligibility

Any submission must involve at least one investigator from a SIOPEN or COG registered institution.

## Review Process

Letters of Intent (LOIs) must be submitted by the deadline 7 September 2018, 23:59 GMT. LOIs will be scientifically reviewed and scored via a process overseen by the Scientific Advisory Board (SAB) of Solving Kids' Cancer UK, subject to identification and mitigation of conflicts of interest. Through competitive review, up to a maximum of 3 LOIs will be selected and invitations made to develop and submit Full Proposals.

Each LOI winner will be expected to produce a Full Proposal for scientific review in early 2019.

## Timeline

<b>Activity</b>	<b>Length of Time</b>	<b>Due Date</b>
<i>RFA Released</i>		<i>27 April 2018</i>
<i>Letters of Intent (LOI)</i>	<i>4 months</i>	<i>7 September 2018, 23:59 GMT</i>
<i>LOI Review &amp; Selection</i>	<i>3 weeks</i>	<i>28 September 2018</i>
<i>Full Study Proposals</i>	<i>4 months</i>	<i>TBA, February 2019</i>
<i>Scientific Review of Proposals</i>	<i>1-2 months</i>	<i>Feb-March 2019</i>
<i>Grant Award Announced</i>		<i>April 2019</i>
<i>Pilot Study Conducted</i>		<i>2020-2022</i>

## Letter of Intent (LOI) Requirements

- I. **Title Page** – Please use the cover sheet provided (on final page of this document).
- II. **Abstract** – Please provide a lay abstract (not to exceed 350 words).
- III. **Concept** – Please provide rationale and potential strategy for the pilot clinical trial (one page).
- IV. **Potential Institutions / Consortia**
- V. **Potential Industry Partners**
- VI. **Description of Proposed Research (knowing that this is preliminary)**
  - a. Primary and secondary objectives.
  - b. Study design.
  - c. Challenges.
    1. Please identify any potential pitfalls in the proposed design that might hamper your ability to achieve the study goals and clarify how such hurdles could be managed.
  - d. Preliminary statistical plan.
    1. How many subjects are necessary to accrue in order to meet your primary objective(s) for the study?
    2. Accrual rate projection and historical data from the centres involved that provide the basis for the accrual projections.
  - e. Plans, if successful, for incorporation into cooperative group frontline treatment strategies.
- VII. **Feasibility**
  - a. Plan to define feasibility and produce a Full Proposal (meetings, timelines and milestones).
  - b. Discuss potential involvement and/or coordination with existing cooperative groups/consortia.

## **VIII. References**

## **IX. Description of Multi-Institutional Resources**

- a. Environment/Personnel.
  - 1. Infrastructure in place to accomplish goals of the proposed study.
  - 2. Delineate specific roles/responsibilities for each cooperating institution.
- b. Deliverability/Feasibility.
  - 1. Please identify any particular regulatory challenges.
  - 2. Please identify any particular challenges with regards to the supply of investigative agents, and details of any discussions that may have taken place thus far.

## **X. Timeline/Deliverables**

- a. Time required for development of Full Study proposal if LOI accepted.
- b. Indicative study timeline to include completion of any preclinical data, IND (US) / IMP (EU) filings, clinical protocol opening, patient accrual, and study completion.

## **XI. Budget**

- a. As part of the LOI, applicants are invited to apply for a Feasibility Grant of \$35,000 to develop a Full Proposal. Details of the amount required, and nature of expenditure must be included. Any request for additional discretionary funding must provide a full breakdown of expenditures and justification.

## **XII. Biosketches – For lead investigators at each site.**

## Key Points of Note

Solving Kids' Cancer and its funding partners stand willing to provide significant joint sponsorship in the region of \$35,000+ for each LOI taken forward and circa \$1,000,000 for the overall winning proposal. An indicative timeline is also provided reflecting a need to move as quickly as possible through the process to the winning pilot study opening for patient recruitment. However, all parties also recognise the importance of this Challenge Grant initiative being driven by researcher innovation allied to realistic costs, timescales, and expectations.

Accordingly, applicants are specifically advised that the following should be included in their Letters of Intent:

- The precise nature and amount of any Feasibility Grant required to develop a Full Proposal.
- Timelines for how long it would take to develop a Full Proposal if the LOI is approved and accepted.
- Evidence that any proposed study is aligned with frontline treatment strategies of major cooperative study groups and can thus be taken forward if successful.

## Review of Your LOI

Solving Kids' Cancer will undertake a non-conflicted scientific review of LOIs for this initiative, overseen by its Scientific Advisory Board (SAB). Comments will be invited from research advocates. Conflicted members of the SAB will not participate in the final LOI selection process.

Reviews will consider the following criteria when evaluating proposals:

- Scientific merit of the proposed research project coupled with the nature and deliverability of plans to commence a clinical trial as stated in the timeline.
- Potential benefit to children with neuroblastoma, and compatibility with future plans of major cooperative study groups in terms of frontline therapy.
- Innovativeness and novelty of approach, agents, and/or study design.
- Investigators' vision, willingness to collaborate, leadership capabilities, and ability to bring together and lead a multi-institution international collaborative clinical trial.

## Questions?

E-mail (preferred): [leona@solvingkidscancer.org.uk](mailto:leona@solvingkidscancer.org.uk) / [research@solvingkidscancer.org.uk](mailto:research@solvingkidscancer.org.uk)



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## Grant Application Cover Sheet

<b>Project Title:</b>	
<b>Principal Investigator:</b>	
<b>Email:</b>	
<b>Telephone:</b>	
<b>Institution Name:</b>	

**We, the undersigned, certify that the statements contained in this grant application are true, complete, and accurate to the best of our knowledge. We understand and agree to comply with any terms set forth in the Request for Applications document, and to abide by any decisions made by Solving Kids' Cancer at their absolute discretion.**

**Signature of Principal Investigator:**

**Date:**

**Signature of Institution Authorized Official:**

**Date:**

**Name and Title of Authorized Official:**

Please submit this grant cover page as part of your application.  
Signatures may be provided electronically or via a scanned original.

**Solving Kids' Cancer**  
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