2020 PEDIATRIC BRAIN TUMOR FOUNDATION REQUEST FOR PROPOSALS (RFP)
GRANT FOR DRUG DELIVERY RESEARCH IN PEDIATRIC NEURO-ONCOLOGY

NOTE: This RFP was updated on March 23, 2020 to reflect an extension of the periods of application submission and the project start date. Updated timeline can be found in the Eligibility and Timeline, Letter of Intent (LOI), and Full Proposal sections with all updated dates noted in red. Please email jsalcido@curethekids.org with any questions.

As the world’s leading nonprofit dedicated to children and teens with brain tumors, the Pediatric Brain Tumor Foundation’s mission is to care for families along their journey, cure all childhood brain tumors, and help survivors and families thrive. Since 1991, we have funded and partnered with organizations to fund more than $45.7 million in scientific discovery to increase survivorship, improve quality of life, and ultimately eliminate pediatric brain tumors. We also provide emotional, informational, and financial support to help families navigate their journey, including the Starfolio Resource Notebook for the newly diagnosed, emergency financial assistance Butterfly Fund, and award-winning Imaginary Friend Society video series. Our signature Ride for Kids, Starry Night, and Vs. Cancer events rally supporters across the country, and regional offices provide critical on-the-ground support to families. Visit www.curethekids.org/mission to learn more.

REQUEST SPECIFICS

Drug delivery is a major challenge to effectively translating validated laboratory findings into clinical success against CNS tumors. The blood-brain barrier (BBB), the blood-tumor barrier (BTB), and the distribution of drugs through the brain parenchyma to tumor cells are significant obstacles to the effective delivery of pharmaceuticals and biologics to the differing brain tumor types. Overcoming these barriers is essential for improving treatment responses in pediatric neuro-oncology.

Guided by input from the PBTF’s Research Advisory Network and discussions at the foundation’s 2019 Translating Discoveries to Cure the Kids (TD2) research conference, the PBTF requests proposals for research that will advance innovative platforms for enhancing or evaluating drug delivery and drug distribution, or for reducing drug efflux.

The proposed research must focus on drug delivery for treating brain tumors in children and/or adolescents. Innovative basic science or translational projects that seek to advance drug delivery to children and/or adolescents are encouraged. Research proposals of special interest to the PBTF are ones likely to generate findings instrumental to advancing treatment options or assessing treatment efficacy. Key research topics of interest include, but are not restricted to, the following:

- Systemic or regional drug delivery approaches for crossing or circumventing the BBB
- Novel biomaterials for drug delivery to the tumor

Determining and achieving biologically effective drug exposure
• Surrogate tracers or biomarkers of drug concentration at the tumor
• Biomarkers of target inhibition
• Characterization of regional variation in BBB permeability
• Strategies for combination drug delivery
• Preclinical measures of biodistribution predictive of clinical performance
• Mechanistic studies of 1) drug delivery by CSF infusion, 2) the relationship between drug concentration in interstitial fluid versus cerebrospinal fluid, or 3) drug distribution across tissue, cellular, and fluid compartments

Proposals with implications solely specific to engineering a particular drug for enhanced delivery or biodistribution are not considered responsive to this RFP.

<table>
<thead>
<tr>
<th>Funding period</th>
<th>Two years</th>
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<tr>
<td>Total budget requested</td>
<td>Up to $200,000 USD total (up to $100,000 USD per year).</td>
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<td>o The PBTF’s funds may only be used to cover direct costs; indirect costs are not negotiated. Funds are for costs related to the research project, including personnel salary at the institution, supplies, and other expenses.</td>
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<tr>
<td>Total funds to be distributed</td>
<td>Up to $200,000 USD</td>
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<td>Online application process</td>
<td>Applicants for the PBTF’s Drug Delivery grant must submit a Letter of Intent (LOI) online as a PDF document. Applicants subsequently selected as finalists will be required to submit a Full Proposal as a PDF document.</td>
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<td>Review</td>
<td>LOIs and Full Proposals will be independently assessed for scientific, technical, and clinical impact by a group of researchers and physician-scientists in pediatric neuro-oncology. Finalists must be available for a phone interview with the PBTF.</td>
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ELIGIBILITY AND TIMELINE
• Eligibility:
The lead Principal Investigator on the application, i.e., the Applicant, must have an MD, PhD, or DO degree and must be a faculty member at an academic institution and, if in the United States, eligible to apply for NIH funding. Applicant may be at an academic institution in the United States or any other country (institution must have IRS 501(c)3 status or equivalent if outside the U.S.)

- **Issue date of RFP:** February 25, 2020
- **Period for submission of Letter of Intent (LOI):** February 25 through July 6, 2020
- **Deadline for submission of LOI:** July 6, 2020 at 5 p.m. Eastern
- **Period for submission of Full Proposal (Finalists only):** August 19 through October 26, 2020
- **Deadline for submission of Full Proposal:** October 26, 2020 at 5 p.m. Eastern
- **Phone interview of finalists with the PBTF:** Applicants invited to submit a Full Proposal are considered finalists and must be available for a phone interview on one of the following three dates: December 10, December 11, or December 14, 2020
- **Notification of outcome of reviews:**
  - Applicants will be notified of the outcome of the review of LOIs by August 18, 2020
  - Finalists will be notified of the outcome of the review of Full Proposals by December 16, 2020.
- **Project start date:** February 15, 2021
- **Project end date:** February 14, 2023

Applicants who have questions about eligibility are encouraged to contact Joanne Salcido at the PBTF via email at jsalcido@curethekids.org before submitting a Letter of Intent.

**HOW TO APPLY**

Applicants must use the PBTF’s online application process for submitting all requested materials. Applicants fill out a form online to provide basic information by direct input or by selection from dropdown menus. They also submit a Letter of Intent and, if selected as a finalist, a Full Proposal (see details on content below).

The Letter of Intent and Full Proposal documents must:
- Not exceed the maximum page allowances specified
- Use minimum 11-point font and have at least ½-inch margins
- Have content organized by headings as specified (see below); no additional content will be accepted

Inquiries about the application process and eligibility requirements can be directed to Joanne Salcido at jsalcido@curethekids.org. The PBTF does not set up meetings or phone calls to discuss the specifics of any application.

**NOTE:** The PBTF supports the principles of open science. Although a complete data sharing plan is not required for the Letter of Intent, there should be acknowledgement of the intent for data sharing within
the narrative. Full Proposals will require a data sharing plan that includes sharing of scientific results and protocols through peer-review publication in conjunction with general availability of underlying raw data. The PBTF expects the projects will share both positive and negative findings with the broader neuro-oncology community.

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**Letter of Intent (LOI)**
LOIs written in response to the RFP issued on February 25, 2020 will be accepted online only, and the submission deadline is **Monday, July 6, 2020 at 5 p.m. Eastern.**

The Letter of Intent must be uploaded as a PDF file labeled: LastName_FirstName_LetterOfIntent_PBTF-DrugDelivery2020

The first review of applications is solely based on the contents of the Letter of Intent. The information requested below should therefore be very clearly and effectively communicated.

The contents of the Letter of Intent must be in the order indicated below by headings I-V and respective subheadings:

**I. General Information** (maximum half page)
- **Principal Investigator (PI) -** provide name, degree(s), institution, and faculty position
- **Research Project Title**
- **Total Funds Requested - in USD**
- **Co-Investigator(s) -** if applicable, provide name, degree(s), institution, and faculty position; denote whether the Investigator is a Co-PI or collaborator; clearly state the advantage of the co-investigator’s expertise to the success of the proposal

**II. Proposal Outline** (maximum 1 page)
- **Background and Specific Aims –** figures should be used judiciously and accompanying legends brief
- **Scientific Approach**
- **Implications of Positive and Negative Results for Next Steps**

**III. References** (maximum 10 pages)
- No more than 10 references to relevant publications may be listed. Do not include appendices or other attachments.

**IV. Biographical Sketch for PI(s) -** NIH biosketch format (maximum 5 pages)
- For Principal Investigator(s) a biographical sketch in the NIH biosketch format is required, i.e., OMB No. 0925-0001 and 0925-0002 (Rev. 9/17 Approved Through 3/31/2020). The Research Support section of
the biosketch (Section D) must include federally and non-federally funded ongoing research, completed projects and pending support to date.

V. About Collaborator(s), if applicable (maximum 150 words per Collaborator)
Provide a brief description of qualifications and anticipated contribution to the project.

Full Proposal
Full Proposals are submitted by invitation only, pursuant to the outcome of the review of LOIs. Full Proposals will be accepted online only, and the deadline is **Monday, October 26, 2020 at 5 p.m. Eastern**.

The Full Proposal must be uploaded as a PDF file labeled:
LastName_FirstName_ProposalNarrative_PBTF-DrugDelivery2020

The contents of the Proposal Narrative must be in the order indicated below by headings I-V and respective subheadings.

**I. Project Description** (maximum 6 pages)
Principal Investigator and Co-Investigator(s) - provide name, degree(s), institution, and faculty position
Research Project Title
Scientific Background and Rationale
Potential Clinical Impact of Findings - describe the clinical path forward
Preliminary Data – may include a description of existing research lines (projects, other grants in your labs/institutions) that will be leveraged for this project, if applicable
Specialized Resources - List any banked biospecimens, clinical images, or genomics data that will be leveraged for these studies
Specific Aims
Methods
Milestones and Project Timeline
Data Sharing Plan - include sharing of scientific results and protocols through peer-review publication in conjunction with general availability of underlying raw data
Major Challenges, Potential Project Pitfalls, and Back-up Plans
Status of Required Institutional Approvals - Indicate status of human subjects or animal research and drug procurement; if pending, indicate the date approval is expected and anticipated impact on the project timeline

**NOTE:** Research using animals must adhere to federal and state laws and must follow the guidelines put forth by the NIH Office of Laboratory Animal Welfare, whether conducted at U.S. or foreign institutions. Use of patient specimens and/or data must conform to IRB-approved usage.

**II. Budget** (maximum 2 pages)
Use NIH format for detailed budget for entire project period (1 page per year for the budget). The PBTF’s funds may only be used to cover direct costs; indirect costs are not negotiated. Funds are for costs related to the research project, including personnel salary at the institution, supplies, and other expenses.

III. Budget Justification (maximum 1 page)

IV. References
List scientific publications cited in the Project Description (Section I).

V. Letter of Institutional Support

AWARDEE REQUIREMENTS
Requirements of the PBTF’s 2020 Drug Delivery Research grantee include:

- Full execution of Contract Agreement between the PI’s institution and the PBTF; managing subcontracts is the responsibility of the lead PI’s institution
- Project status update via teleconference: mid-year for Years 1 and 2
- Written Summary Progress Reports: at the end of Years 1 and 2
- Attendance at the PBTF’s scientific meeting, Translating Discoveries to Cure the Kids, as requested

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We look forward to receiving your application.