Boston Children's Hospital Translational Research Program (TRP) Research Grant Application Instructions

DEADLINES

Letter of Intent: February 2, 2024 Final applications: April 26, 2024 Funds available: July 1, 2024

Please submit LOI's and applications to TRP@childrens.harvard.edu

For questions regarding these instructions, please contact the TRP trp@childrens.harvard.edu

- 1. **Background:** The mission of the TRP is to stimulate the development of non-clinical and human clinical trials seeking to improve the care of children and to ensure adequate infrastructure to support non-clinical and clinical translational research projects.
- 2. **Definitions:** Translational research is defined as the translation of observations made in the research laboratories and clinical services at BCH and elsewhere into clinical studies involving humans, or the use of clinical observations to define basic research hypotheses or studies. Innovative use of clinical material in basic laboratories is considered translational research. A research study qualifies as translational if it:
 - i. Uses new approaches or discoveries to address clinical problems.
 - ii. Develops new experimental or diagnostic reagents and procedures to diagnose and treat childhood illnesses and condition.
 - iii. Develops new models of human diseases and uses them to inform clinical issues involving children.
 - iv. Adapts approaches already in place in other disciplines to address pediatric diseases.

Non-clinical Translational Research: Non-clinical translational research is laboratory research that leads to a plan or design for new or improved elements of child health care, whether intended for internal use or use by others outside of BCH. It includes the conceptual formulation, design, pre-clinical, and post-clinical testing of a range of diagnostic and therapeutic products and procedures, as well as health services processes. The term "non-clinical" is preferred to "pre-clinical", because non-clinical also encompasses laboratory testing done after the introduction and testing of an agent, device, or procedure in humans.

<u>Clinical Translational Research</u>: Clinical translational research is confirmation in human clinical testing or observation that the products, procedures and health services processes created to improve child health deliver the expected benefits without unacceptable side effects. This category includes feasibility and safety pilot studies and traditional Phase I clinical trials, with assessments of safety and clinical effectiveness. In addition, clinical translational research encompasses the use of clinical observations or reagents to drive basic laboratory studies. Phase II trials will rarely be considered translational research.

3. Purpose of grants: Proposed research projects must be related to the goals of the Translational Research Program (TRP). In brief, the TRP has been established to encourage the development of interactions between basic scientists and clinicians to foster the development of non-clinical and clinical investigations for children with serious diseases. Thus, studies which include the participation of both clinicians and basic scientists are preferred. The ultimate goal of the TRP is to facilitate clinical trials that utilize the findings generated through this funding mechanism.

4. Types of Grants Available:

1. New research proposals: These grants are for one year of support. The maximum allowable budget (direct costs) is \$100,000. The number of awardees will be determined by the quality of the proposals, the total amounts of the requested budgets of sufficiently meritorious proposals, and available funds. It is anticipated that 5-7 awards will be made in the \$50,000-\$100,000 range. A second year of funding is possible in rare circumstances; competing renewal applications for a second year of funding will be considered during next year's grant review cycle.

- Competing renewal applications: For those projects previously supported by the TRP, a second year of support may be sought. These applications will be reviewed in the same manner as new applications. Applications must include a "Progress to Date" section and must convincingly justify the need for more support.
- 5. Cost-sharing: Applications for TRP Pilot Grants will require a specific sign-off from Department Chair-persons indicating their commitment to provide a 'match' (30% of direct costs awarded) in funding for successful applications. For the Department of Medicine, the Division Chief's signature is required. The TRP will continue to provide rigorous, multi-disciplinary peer-review for these applications, 70% funding and individual guidance to each funded project during the funding period.
- **6. Eligibility**: Applications will be accepted from all faculty of Boston Children's Hospital, including nursing, health outcomes and other health care faculty with advanced degrees (M.D., Ph.D., M.D.-Ph.D., or equivalent). Clusters of investigators spanning disciplines and programs made up of basic and clinical faculty are strongly encouraged. **Fellows are noteligible.**
- 7. **Process**: The initial application will consist of a 2-page Letter of Intent (LOI). The LOI will be screened to examine if the proposed research project supports the goals of the TRP. The screening process will be performed by a multidisciplinary committee representing established researchers at BCH and chaired by the Director of the Translational Research Program. Following the initial screening, an invitation will be sent to selected investigators to submit the full application.
- **8.** Letter of intent: For research proposals, the LOI consists of the application face page and 1-2 pages of the hypothesis and specific aims. The aims should include a brief description of the research design and methods.
 - All LOI applications must be submitted to TRP@childrens.harvard.edu. An email confirmation of receipt will be returned to the applicant. **The LOI must be received by 5 pm on February 2, 2024**.
- 9. Signatures: The signature of the primary investigator (and co-investigator) is required in the Letter of Intent initial application. Additionally, the signature of the primary investigator's Department Chair is required and indicates his/her commitment to providing 30% match of direct costs (plus associated applicable overhead) should the proposal be awarded. For the Department of Medicine, the Division Chief's signature is required.
- 10. Full applications (must be invited following review of LOI): Notifications will be sent out mid-March.

Invited, full applications must be submitted in single spaced text, one-half inch margins, and no smaller than an 11-point font. Arial or Helvetica typeface is preferred. The primary applicant's name must appear in the upper right-hand corner of each page. **Proposal text must be limited to five pages** (including figures but excluding references). Standard PHS 398 forms for budget, biosketch, other support, and resources may be used and may be submitted as separate files.

Required format: Applications must be submitted electronically (ideally, this includes an electronic version of the letter of support).

Send a PDF file of assembled proposal to TRP@childrens.harvard.edu. Application forms (modified from PHS 398) are attached.

11. Letter of Support: Full applications must include a letter of support from the primary applicant's chairperson. Included in the letter of support must be a statement regarding the priority of the research proposal for the division, particularly as it relates to patient resources. The signature of the primary investigator's Department Chair (for DoM. the Pl's Division Chief's signature) is required and indicates his/her commitment to providing 30% match of direct costs (plus associated applicable overhead) should the proposal be awarded

Translational Research Program 2024 Pilot Grants Letter of Intent: 2 February 2024

1.	Title of project:	
2.	Renewal: No Yes	
3.	Principal Investigator:	
	a. Name and Degree(s):	
	b. Position title:	
	c. Division:	
	d. Department:	
	e. Mailing address:	
	f. Email address:	
	g. Phone number:	
4.	Co-Investigator:	
	a. Name and Degree(s):	
	b. Position title:	
	c. Division:	
	d. Department:	
	e. Mailing address:	
	f. Email address:	
	g. Phone number:	
5.	Direct costs requested:	
6.	Signatures: The undersigned reviewed this application for a BCH TRP research award and are familiated with the policies, terms, and conditions concerning research support and accept the obligation to consulty with all such policies, terms, and conditions. a. Signature of Principal Investigator:	
	b. Signature of Co-Investigator	
	c. Signature of Department Chairperson	

Signature of Department Chairperson (for Department of Medicine, the Division Chief's signature is required) indicates his/her commitment to providing 30% match of direct costs (plus associated applicable overhead) should the proposal be awarded. Applications without appropriate signature will be returned to investigator without review.