

**Boston Children's Hospital
Translational Research Program (TRP)
Pappendick Family Therapeutic Acceleration Award**

**Final Applications Due: 2 March 2020
Funding Commences: 1 July 2020**

Please submit all applications to TRP@childrens.harvard.edu.

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

1. **Background:** The goal of the Pappendick Family Therapeutic Acceleration Award is to facilitate investigators getting their late preclinical and early clinical phase 1 studies accomplished in order to allow investigators to more rapidly pursue their research which could ultimately impact the lives of pediatric patients suffering from serious or life-threatening diseases. The Translational Research Program (TRP) has created this new initiative to provide support to investigators in two spheres:
 - Late pre-clinical studies.
 - Early clinical phase 1 studies
2. **Purpose of grant:** The program seeks to accelerate studies with clear paths to market/IP.
3. **Funding details:** Funding through the Pappendick Family Award is available in the form of two-year awards with up to \$100k/year (inclusive of 20% overhead) available. The TRP anticipates awarding two awards per year.
4. **Eligibility:** Applications will be accepted from Principal Investigators (PIs) who are full-time faculty of Boston Children's Hospital. For phase 1 studies, at time of application, if not already open and accruing patients, the trial should be ready to open within the upcoming 6-months. Those studies representing translation of scientific discoveries from BCH, particularly first in human studies, or trials in which BCH is the lead site will have priority. Any IP generated is expected to remain at BCH.
5. **Process:** Applications will be accepted on yearly basis and will be reviewed by an external review committee consisting of translational research and clinical trial experts from outside Boston Children's Hospital as well as members of the Venture Philanthropy Network.

Review criteria: Applications will be prioritized for funding based on the review panel's evaluation of the following:

1. The likely impact of research on child health with a clear path to market.
2. The role of BCH basic/discovery and translational research in development of the research and, compelling nature of the need.
3. The track record of the investigative team in carrying out late preclinical and/or human early phase therapeutic and device trials.

These aspects should be covered in the application.

6. **Signatures:** The signature of the primary investigator (and co-investigator) is required. Additionally, the signature of the primary investigator's Department Chairman or Division Chief's signature is required.
7. **Full applications:** Research plan/proposal (not to exceed 5 pages, including figures but excluding references) should include a summary of the study and its goal as well as a strong justification for why funding is needed and an explanation of how this funding will accelerate the research and path to market. Proposal text must be limited to five pages (including figures but excluding references).

Additional items to be included as an appendix (not included in 5- page limit) are requested:

- IRB approval letter (if applicable)
- FDA (IND/IDE) approval (if applicable)
- Summary notes from IND/IDE Review Group (IIRG) meeting (if appropriate)
- Current (if any) funding for study
- Reviewer comments from grants that fund any part of the trial

Required format: *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. Standard NIH forms for abstracts, NIH biosketch, and other support may be used and may be submitted as separate files. Applications must be submitted electronically, including the letter of support from Department Chair/Division Chief.

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

8. **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 importance of the research to the field and priority of the trial for the department/division, including prioritization of the patient population to be enrolled in the trial. The Chairperson should affirm that the applicant will have the support of the Department/Division to carry out the proposed studies.
9. **Composition of Research Proposal:** Invited research proposals should include:
 - a. Face Page
 - b. Abstracts (scientific and lay)
 - c. Table of Contents
 - d. Detailed Budget
 - e. Budget justification
 - f. Biosketch(es) (include PI and co-investigator; NIH format)
 - g. Other support
 - h. Research Plan (5-page limit), including the following items: The role of BCH basic/discovery and translational research in development of the clinical trial, compelling nature of the need and the track record of the investigative team in carrying out human early phase therapeutic and device trials.
 - i. Literature cited
 - j. Appendix
 - IRB approval (if applicable)
 - FDA approval (if applicable)
 - Summary notes from IIRG meeting (if appropriate)
 - Current funding outline for study
 - Reviewer comments from grants that fund any part of the trial
 - Letters of support from Department/Division chairperson.
 - Letters of support collaborators or consultants are optional.

Translational Research Program

2020 Pappendick Family Therapeutic Acceleration Award

Final Application Due: 2 March 2020

1. Title of project:
2. Principal Investigator:
 - a. Name and Degree(s):
 - b. Position title:
 - c. Division:
 - d. Department:
 - e. Mailing address:
 - f. Email address:
 - g. Phone number:
3. Co-Investigator:
 - a. Name and Degree(s):
 - b. Position title:
 - c. Division:
 - d. Department:
 - e. Mailing address:
 - f. Email address:
 - g. Phone number:
4. Total costs requested:
5. Signatures: *The undersigned reviewed this application for a BCH TRP research award and are familiar with the policies, terms, and conditions concerning research support and accept the obligation to comply with all such policies, terms, and conditions.*
 - a. Signature of Principal Investigator: _____
 - b. Signature of Co-Investigator _____
 - c. Signature of Department Chairperson _____

Principal Investigator (Last, First, Middle):

Scientific Abstract: Using technical language, briefly describe the proposed project in 200 words or less.

Lay Abstract: Using non-technical language, briefly describe the proposed project in 100 words or less.

Principal Investigator/Program Director (Last, First, Middle):

TRANSLATIONAL RESEARCH PROGRAM

APPLICATION CHECKLIST

| | |
|---|--------------------------|
| Face Page and approvals | <input type="checkbox"/> |
| Abstracts: scientific and lay | <input type="checkbox"/> |
| Table of Contents | <input type="checkbox"/> |
| Detailed Budget | <input type="checkbox"/> |
| Budget Justification | <input type="checkbox"/> |
| Biographical Sketch – Principal Investigator (<i>Not to exceed five pages</i>) | <input type="checkbox"/> |
| Other Biographical Sketches (Not to exceed five pages for each) | <input type="checkbox"/> |
| Other Support | <input type="checkbox"/> |
| Resources | <input type="checkbox"/> |
| Research Plan | <input type="checkbox"/> |
| A. Hypothesis and Specific Aims..... | <input type="checkbox"/> |
| B. Background and Significance..... | <input type="checkbox"/> |
| C. Preliminary Studies/Progress Report | <input type="checkbox"/> |
| D. Research Design and Methods..... | <input type="checkbox"/> |
| E. Statement of the role of BCH basic/discovery and translational research in development of the clinical trial | <input type="checkbox"/> |
| F. Statement of commercialization potential (include any issues of intellectual property) | <input type="checkbox"/> |
| G. Literature Cited..... | <input type="checkbox"/> |
| H. Letter from Department of Division Chair | <input type="checkbox"/> |
| I. Letters of Support (e.g., Consultants) | <input type="checkbox"/> |
| | <input type="checkbox"/> |

A-F: not to exceed 5 pages

Principal Investigator/Program Director (Last, First, Middle):

| | | |
|--|------|---------|
| DETAILED BUDGET FOR BUDGET PERIOD DIRECT COSTS ONLY | FROM | THROUGH |
|--|------|---------|

| PERSONNEL <i>(Applicant organization only)</i> | | TYPE APPT. <i>(months)</i> | % EFFORT ON PROJ. | INST. BASE SALARY | DOLLAR AMOUNT REQUESTED <i>(omit cents)</i> | | |
|--|------------------------|----------------------------|-------------------|-------------------|---|-----------------|-------|
| NAME | ROLE ON PROJECT | | | | SALARY REQUESTED | FRINGE BENEFITS | TOTAL |
| | Principal Investigator | | | | | | |
| | | | | | | | |
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| SUBTOTALS → | | | | | | | |

CONSULTANT COSTS

EQUIPMENT *(Itemize)*

SUPPLIES *(Itemize by category)*

TRAVEL

| | |
|--------------------|------------|
| PATIENT CARE COSTS | INPATIENT |
| | OUTPATIENT |

OTHER EXPENSES *(Itemize by category)*

| | |
|--|-----------|
| SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD | \$ |
|--|-----------|

| | | |
|--------------|--|--|
| COST SHARING | Department contribution (30% of total) | |
| | TRP contribution (70% of total) | |

| | |
|---|-----------|
| TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD <i>(Item 10, Face Page)</i> → | \$ |
|---|-----------|

Principal Investigator (Last, First, Middle):

BUDGET JUSTIFICATION

Principal Investigator (Last, first, middle):

OTHER SUPPORT

Provide active support for all key personnel. **Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.** Training awards, prizes, or gifts do not need to be included.

There is no "form page" for other support. Information on other support should be provided in the *format* shown below, using continuation pages as necessary. **Include the principal investigator's name at the top and number consecutively with the rest of the application.** The sample below is intended to provide guidance regarding the type and extent of information requested. Refer to the specific instructions in Section I. For information pertaining to the use of and policy for other support, see "Policy and Additional Guidance."

Format

NAME OF INDIVIDUAL

ACTIVE/PENDING

| Project Number (Principal Investigator) Source Title of Project (or Subproject) | Dates of Approved/Proposed Project Annual Direct Costs | Percent Effort |
|---|---|----------------|
| The major goals of this project are... | | |

OVERLAP (summarized for each individual)

ACTIVE

PENDING

OVERLAP