

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

**DEADLINES**

**Letter of Intent: February 3, 2012**

**Final applications: April 9, 2012**

**Funds available: July 1, 2012**

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

*For questions regarding these instructions, please contact the TRP [trp@childrens.harvard.edu](mailto: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 CHB 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 CHB. 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.

**Clinical Translational Research:** 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 6-8 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.

2. **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 Chairpersons indicating their commitment to provide a ‘match’ (30% of direct costs awarded) in funding for successful applications.** 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 Children’s Hospital Boston, 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 not eligible.**
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 CHB 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 page (see section 12 below). 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 3, 2012.**

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 Chairman is required and indicates his/her commitment to providing 30% match of direct costs (plus associated applicable overhead) should the proposal be awarded.**

#### 10. Full applications (must be invited following review of LOI):

*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 Chairman is required and indicates his/her commitment to providing 30% match of direct costs (plus associated applicable overhead) should the proposal be awarded**

12. **Composition of research proposal:** Invited research proposals and competing renewals should include:

1. Face page
2. Abstracts (scientific and lay)
3. Tables of contents
4. Detailed Budget (1 year; use PHS 398 form provided)
5. Budget justification
6. Biosketch(es) (include PI and co-investigator; use PHS 398 form)
7. Other support (PHS 398 form)
8. Resources (PHS 398 form)
9. Hypothesis and Specific Aims
10. Background and Significance
11. Preliminary Results or, if 2<sup>nd</sup> year renewal, Progress Report
12. Research Design and Methods
13. Statement of how proposal supports TRP mission
14. \*Statement of Commercialization Potential (include any issues of intellectual property)
15. Statements regarding human subjects and/or animals; include plans to utilize the CRP or CTSU resources
16. Literature cited
17. Consortium/Contractual Arrangements
18. Letter of support from Department/Division chairperson
19. Letters of support from collaborators or consultants  
\*optional

**Translational Research Program  
2011 Pilot Grants  
Letter of Intent: 03 February 2012  
Final Application: 09 April 2012**

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 CHB 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 \_\_\_\_\_

*Signature of Department Chairperson 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.*

Approvals

The following information is requested for invited full applications (not necessary to include with Letter of Intent):

7. Human Subjects Research: \_\_\_ No \_\_\_ Yes
8. Human Subjects Assurance #: \_\_\_\_\_
9. NIH-Defined Phase I Clinical Trial: \_\_\_ No \_\_\_ Yes
10. Human Subjects Protection Certification: \_\_\_ No \_\_\_ Yes (Certification date \_\_\_\_\_)
11. Vertebrate Animals: \_\_\_ No \_\_\_ Yes
  - a. IACUC Approval Date \_\_\_\_\_
  - b. Animal Welfare Assurance # \_\_\_\_\_
12. COMS Protocol: \_\_\_ No \_\_\_ Yes (Approval date \_\_\_\_\_; Approval # \_\_\_\_\_)
13. Radiation: \_\_\_ No \_\_\_ Yes (Approval date \_\_\_\_\_)

Principal Investigator (Last, First, Middle):

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**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.

## TRANSLATIONAL RESEARCH PROGRAM

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<b>Biographical Sketch – Principal Investigator</b> ( <i>Not to exceed four pages</i> ) .....	<u>7</u>
<b>Other Biographical Sketches</b> (Not to exceed four pages for each) .....	_____
<b>Other Support</b> .....	_____
<b>Resources</b> .....	_____
<b>Research Plan</b> .....	_____
A. Hypothesis and Specific Aims .....	_____
B. Background and Significance.....	_____
C. Preliminary Studies/Progress Report .....	_____
D. Research Design and Methods .....	_____
E. Statement of how proposal supports TRP mission.....	_____
F. Statement of commercialization potential (include any issues of intellectual property) .....	_____
G. Human Subjects .....	_____
Protection of Human Subjects (Required if Item 7 on the Approval Page is marked “Yes”) .....	_____
Data and Safety Monitoring Plan (Required if Item 9 on the Face Page is marked “Yes” Phase I clinical trial) .....	_____
H. Vertebrate Animals .....	_____
I. Literature Cited .....	_____
J. Consortium/Contractual Arrangements .....	_____
K. Letter from Division Chair .....	_____
L. Letters of Support (e.g., Consultants).....	_____

### Appendix

Number of publications and manuscripts accepted for publication (*not to exceed 5*)

Other items (list): \_\_\_\_\_

Check if  
Appendix is  
Included



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**BUDGET JUSTIFICATION**

[Empty rectangular box for budget justification text]

Principal Investigator (Last, first, middle):

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### BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.  
Follow the sample format for each person. **DO NOT EXCEED FOUR PAGES.**

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NAME		POSITION TITLE	
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY

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**NOTE: The Biographical Sketch may not exceed four pages. Items A and B (together) may not exceed two of the four-page limit. Follow the formats and instructions on the attached sample.**

- A. Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.
- B. Selected peer-reviewed publications (in chronological order).** Do not include publications submitted or in preparation.
- C. Research Support.** List selected ongoing or completed (during the last three years) research projects (federal and non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and your role (e.g. PI, Co-Investigator, Consultant) in the research project. Do not list award amounts or percent effort in projects.

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**Principal Investigator (Last, first, middle):**

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**OTHER SUPPORT**

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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**

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**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

Principal Investigator (Last, First, Middle):

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## **RESOURCES**

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**FACILITIES:** Specify the facilities to be used for the conduct of the proposed research. Indicate the performance sites and describe capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Under "Other," identify support services such as machine shop, electronics shop, and specify the extent to which they will be available to the project. Use continuation pages if necessary.

Laboratory:

Clinical:

Animal:

Computer:

Office:

Other:

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**MAJOR EQUIPMENT:** List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.

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To insert additional documents, select *Tools* from the MS Word menu, then *Unprotect Document*. You will be able to add text and pages as needed.

To continue using the pages before this page, you must protect the document; to protect this document, select *Tools* from the MS Word menu, then *Protect Document*, then *Forms*. You will then be able to enter information into the fields.