

**Children's Hospital, Boston
Translational Research Program (TRP)
Core 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

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:**

Innovative cores: To help build adequate local infrastructure to support translational research, funds are available for the establishment of new cores. Core proposals up to \$50,000 per year for up to two years of TRP funding will be considered.

5. **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.**
6. **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.
7. **Letter of intent:** For core proposals, the LOI consists of the application face page and a 1 page description of the proposal. All LOI applications must be submitted by email 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.**
8. **Signatures:** The signature of each primary investigator is sufficient in the Letter of Intent initial application. **The signatures of all investigators and their respective division chairperson(s) are required for the full application.**
9. **Full Applications:** Must be *invited* following review of LOI.

Applications must also be submitted electronically (except letter of support, unless it is also available electronically). Send a PDF file of assembled proposal to TRP@childrens.harvard.edu. Application forms (modified from PHS 398) are attached.

Full proposals, if invited, 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.

Full application must be received by 5pm, April 9, 2012.

10. **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.
11. **Composition of core proposals:** Cores supported by the TRP may include laboratory and clinical facilities, equipment, and services that will be shared by multiple investigators.

The TRP is primarily interested in supporting new, innovative cores that promote the mission of building a local or networked infrastructure for conducting preclinical or translational research. Established cores seeking bridge or supplemental funding, or cores that primarily support basic (discovery) research, are not likely to be successful through the TRP mechanism.

The core service plan should include a description of the services to be provided and the background and significance for the core. The applicant should present a clear description of methods and services to be provided and (if appropriate) discussion of human subjects protection and inclusion, as well as a data safety monitoring plan/board. Cores may contain a non-hypothesis driven research activity, provided that the research is designed to improve core services. The applicant should clearly present the facilities, resources, and professional skills that the core will provide to investigators. A plan for funding of the core beyond the two year period supported by the TRP is essential.

The core proposal should also include a discussion of the decision-making processes for core activities including prioritization of service and allocation of resources, the establishment of any oversight committees, and the planned mechanisms for promoting communication and collaboration among users of the core.

To aid in the review, it is suggested that a table, to show the anticipated use of the core by each investigator, be included in the application. Justify the core by discussing ways in which the centralized services improve quality control, produce an economy of effort, and/or save overall costs for investigators (benefits of core).

Thus, the core application should include:

1. Face page (check all appropriate COMS, IACUC, IRB, or Radiation Safety approvals or indicate pending if submitted))
2. Abstracts (scientific and lay)
3. Table of Contents
4. Budget (1-2 years; use PHS 398 form provided)
5. Budget justification
6. Biosketch(es) (include PI and co-investigators; use PHS 398 form)
7. Other support for core (PHS 398 form)
8. Resources of PI (PHS 398 form)
9. Background and Significance
10. Methods and Services provided by core
11. Anticipated Users (include table if possible)
12. Benefits of Core to Users
13. Plans for Allocation of Core Resources
14. Plans for Oversight
15. Methods for Protecting Human Subjects
16. Vertebrate Animals
17. Facilities and Resources for Core
18. Plans for Future Core Support
19. Statement of how core supports TRP mission
20. Letter of support from division chairperson

The merit of each core proposal will be judged on the following criteria:

1. Quality of the science supported by the core
2. Quality of the product and cost-efficiency of the service
3. Potential breadth of users (cores anticipated to be utilized by multiple investigators in multiple divisions will be given priority)
4. Justification of the budget request
5. Potential effectiveness for strengthening the infrastructure in the basic, clinical and/or populations sciences as they relate to promoting translational research
6. Potential effectiveness for taking advantage of scientific opportunities afforded by other investigators' proposed studies
7. Plans for continued funding of the core following exhaustion of TRP funds

**Translational Research Program
2011 Core 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 Division Chief of PI _____
 - d. Signature of Division Chief of Co-PI _____

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/Program Director (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.

TRANSLATIONAL RESEARCH PROGRAM

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Face Page and approvals	<u>1-2</u>
Abstracts: scientific and lay	<u>3</u>
Table of Contents	<u>4</u>
Detailed Budget	<u>5</u>
Budget Justification	<u>6</u>
Biographical Sketch – Principal Investigator/Program Director (<i>Not to exceed four pages</i>)	<u>7</u>
Other Biographical Sketches (Not to exceed four pages for each)	_____
Other Support	_____
Resources	_____
Research Plan	_____
A. Background and Significance.....	_____
B. Methods and Services Provided by Core.....	_____
C. Anticipated Users (include table if possible).....	_____
D. Benefits of Core to Users	_____
E. Plans for Allocation of Core Resources.....	_____
F. Plans for Oversight	_____
G. Methods for Protecting Human Subjects.....	_____
H. Vertebrate Animals.....	_____
I. Facilities and Resources for Core	_____
J. Plans for Future Core Support	_____
K. Statement of how core supports TRP mission	_____
L. Literature Cited	_____
M. Consortium/Contractual Arrangements	_____
N. Letter from Division Chair	_____
O. Letters of Support (e.g., Consultants).....	_____

} Not to exceed 5 pages

Appendix (*Five collated sets. No page numbering necessary for Appendix.*)

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

Other items (list): _____

Check if
Appendix is
Included

BUDGET JUSTIFICATION

[Empty rectangular box for budget justification text]

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.**

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

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.

Principal Investigator/Program Director (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 (<i>or Subproject</i>)	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/Program Director (Last, First, Middle):

RESOURCES

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:

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

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.