

Boston Children's Hospital
Translational Research Program
Application Instructions for the Translational Investigator Service:
Category: Junior Investigator

Applications due *January 13, 2023*

Funding begins July 2023

Overview of the Translational Investigator Service

The TIS was established in order to identify and support the development of faculty-scientists who will become the national and international leaders in the translational research paradigm. Major highlights of this program include providing individuals with the necessary financial, time, and educational resources to be able to conduct meaningful translational research. Success of this program will 1) facilitate the rapid translation of discovery sciences into human trials; 2) facilitate the utilization of human patient resources for the purpose of advancing scientific discovery; and 3) position Boston Children's Hospital for successful competition for NIH, disease-specific foundation, pharmaceutical, and philanthropy financial support.

The TIS is intended to be a multidisciplinary cadre of outstanding faculty scientists with strong scientific and clinical backgrounds and significant productivity histories. These attributes, combined with strong leadership skills, will help to increase their potential as future leaders in translational research.

Review and selection of finalists will be done by members of the Clinical and Translational Research Executive Committee (CTREC).

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 conditions.
- 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 “preclinical”, 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.

Eligibility

Individuals must be nominated by their departments. Multiple individuals can be nominated by each department. MD’s or MD/PhD’s who are members of the Boston Children’s Hospital faculty and have held the rank of Assistant Professor for no more than three years are eligible. This award is intended for investigators at early stages of their independent research careers. It is suitable for those in the final years of a career development award (e.g. K08). Emphasis will be placed upon training and productivity during faculty development award period.

Review Criteria

- a. Excellence of the applicant. Prior education and training. Letters of recommendation commenting on the predicted future success in completion of translational research and external funding will be a primary focus during review process.
- b. Thoughtfulness of career development and research plans, and a clear commitment to translational research. Proposal must clearly describe how the research conforms to the above definitions of Non-clinical or Clinical Translational Research. Adherence to the spirit of the “handshake rule” is desired where the investigator personally meets with or is otherwise directly involved with the care of each patient involved in the study. Clinical specialties that do not involve direct patient medical or surgical care (e.g. radiology or pathology) would still be considered to have “a handshake” if the proposal included research related to patients in which the investigator is involved in direct evaluations of patients in the study. Proposed projects which use identified patient materials and/or data would be supported.

- c. Special attention will be paid to the demonstration of a clear linkage between the basic and clinical research in the proposal. Evidence to support the capability of the applicant to successfully apply basic research to clinically relevant problems or plans to use of patient resources to inform basic research should be highlighted. Particular emphasis will be placed in the review process on proposals where there is a focus on executing human trials using BCH-driven science and laboratory discoveries from this institution. Collaborations between basic researchers and clinicians at BCH and the translational investigator should be clearly and explicitly outlined.
- d. Support and commitment by the applicant's department and/or division to protecting the applicant's time, providing matching salary support and the capacity of the department/division to successfully engage in translational research, including the prioritization of this research with respect to department/division, patient, administrative and financial resources.

Review Process

Applications will be reviewed by members of the Clinical and Translational Research Executive Committee. Top-ranked applicants will then be asked to participate in a panel interview with senior BCH translational researchers.

Details—Funding and Time Commitment

1. Funding will commence on July 1, 2023. Duration for 5 years.
2. Salary and Fringe: Cost-share between the Translational Research Program (TRP) and Divisional/Departmental Funds:
 - a. The TRP will provide funds up to \$62,500 plus fringe for investigator's salary.
 - b. Remaining salary funds should be derived from professional fees, grants and/or division/department investments.
 - c. Expectation is to develop NIH funding (e.g. R21, clinical R01's, PPG's and other programmatic or center grants).
3. Minimum 50% of time must be devoted to translational research.
4. TRP will provide additional funds for research support up to \$40,000/yr total cost (inclusive of directs, costs s,(incl. fringe as applicable) plus indirects and/or fringe) with no carry over from year to year.
 - a. This supplemental funding can be used to fund clinical research

associate or research nurse support as well as laboratory supplies.

- b. Other protocol-specific uses of this funding will be considered (e.g. use of core facilities such as DNA sequencing or histology services).
- c. A detailed budget must be approved annually by the Associate Director of the TRP for this supplemental funding.

5. Chosen investigators will be expected to participate in various programmatic activities, including training activities, such as:

- a. Participation at an annual off-site TRP retreat is required.
- b. Participation in an intensive clinical trial or clinical investigation course such as the MGH Clinical Trials Course (given annually Sept/Oct, for 8 weeks, 2 hrs/wk), or Harvard Catalyst courses such as the Intensive Training in Translational Medicine course (2 week course, offered annually in July) or the Introduction to Clinical Investigation course (5 day course, offered three times per year).
- c. Regularly scheduled meetings of program participants (including, but not limited to, presentations at quarterly meetings, monthly lecture series)

6. Annual progress reports should include:

- a. Summary of research accomplishments. This should be a scientific overview of the project's goals and progress and should not exceed 4 pages. Please also include a description of work to be done in the upcoming year.
- b. One paragraph lay summary (at a level appropriate for distribution to Hospital Board of Trustees and interested donors) of research and accomplishments.
- c. PDF copies of all publications from the past year (citing of TRP funding from BCH is expected).
- d. Updated list of current and pending funding.
- e. List of conferences attended, and talks given in the past year.
- f. Summary of how TRP research supported funds were used in prior year and plans for current year's use.

Application— MUST BE SUBMITTED IN PDF FORMAT

(Please send all application materials to TRP@childrens.harvard.edu)

Please submit files with the following naming convention (Applicant's last name-file #Jr). File number should correspond to the following list:

1. Updated Curriculum Vitae (Harvard format)
2. General Statement of research interests/plans - limit to 3 single-spaced pages (not including references), 12-point type. Please include a discussion of how proposed research will be “translational” in scope, with a focus on the linkage between basic and clinical research.
3. Career development plan and the impact the TIS award would have - limit to 3 single-spaced pages, 12-point type. Additionally, please address how prior training/education contributes to the likelihood of success as an independent translational researcher in the future.
4. Budget (1 year; use PHS 398 form) and Budget justification
5. Other sources of funding (current and pending), including any startup funds in new NIH Other Support format.
6. Letter of support from Division/Department head. The letter must confirm:
 - a. Applicant's academic appointment
 - b. The division's/department's commitment to the applicant's research and training as a translational scientist, including the guarantee of protected time (minimum 50%) for the applicant to pursue his/her research endeavors.
 - c. The letter should also discuss the priority of translational research within the Department/Division, including translational research infrastructure, specific patient populations, basic science strengths can be leveraged for translational studies and translational research space.
7. Three additional letters of recommendation should be submitted directly to Judy Fleming, Assoc. Director, TRP (Judith.fleming@childrens.harvard.edu) by the application deadline. Of the three letters, one recommender must be from outside BCH. Please include a list of recommenders with contact information with application.