

Boston Children's Hospital

Translational Research Program

Application Instructions for the Translational Investigator Service (TIS)

Category: Mentored

Applications due May 6, 2024

Funding begins September 2024

Overview of the Mentored Translational Investigator Service award

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 mentored TIS (mTIS) award is intended provide personalized support and education to promising young trainees - those who have completed fellowship training but are not yet fully independent investigators - who are interested in translational research, effectively building the pipeline of outstanding translational investigators at BCH. The TIS program is a multidisciplinary cadre of outstanding faculty scientists with strong scientific and clinical backgrounds, significant productivity histories, and strong leadership skills. Each mTIS awardee will be officially paired with an appropriate mentor from the pool of current senior TIS members as well as with a mentor from outside of BCH who is from the local biotech/pharma/venture capital community. Regular meetings with these mentors, in addition to participation in ongoing TIS programs including TRP sponsored events including the annual investigator retreat and symposium, will be required. The goal of the mentor/mentee relationship is to help develop a plan for developing a robust translational research program with appropriate coursework where necessary, in addition to helping to navigate the various institutional resources that are encountered (e.g. biostatistics, IRB, regulatory).

Review and selection of finalists will be done by the Clinical and Translational Research Executive Committee (CTREC) and current and past senior TIS

investigators.

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 have completed clinical training, are eligible. PhD’s are not eligible. This award is intended for investigators at early stages of their research careers. Assistant Professors are not eligible.

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, 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 senior members of the TIS and selected 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 in September 2024. Award duration is 3 years.
2. The TRP will provide up to \$300,000 (directs) over 3 years to be spent at the investigator’s discretion in consultation with their mentor. In addition, the TRP will cover the applicable indirect costs. Salaries, supplies, travel expenses etc. are all appropriate and allowable expenses.

3. Minimum 50% of time must be devoted to translational research.

4. Chosen investigators will be expected to participate in various programmatic activities, including training activities, such as:
 - a. The Introduction to Clinical Research Course run by the BCH ICCTR.
 - b. Participation at an annual off-site retreat is required as well as the annual TRP sponsored symposium.
 - c. Participation in relevant courses (sponsored by BCH, Catalyst, other institutions)
 - d. Regularly scheduled meetings with mentors.

6. Annual progress reports should include:
 - a. Summary of current state and development of mentored research plan and 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. Review of mentoring meetings, including dates and action plans.
 - c. One paragraph lay summary (at a level appropriate for distribution to Hospital Board of Trustees and interested donors) of research and accomplishments.
 - d. PDF copies of all publications from the past year (citing of TRP funding from BCH is expected).
 - e. Updated list of current and pending funding.
 - f. List of conferences attended, and talks given in the past year.
 - g. 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 #). File number should correspond to the following list:

1. Updated Curriculum Vitae (Harvard format)
2. 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.
3. Career development plan and the impact this award would have. Additionally, please address how prior training/education contributes to the likelihood of success as an independent translational researcher in the future. (3 pages)
4. Budget (1 year; use PHS 398 form). Budget justification.
5. 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.
6. Other sources of funding (current and pending), including any startup funds.
7. Three letters of recommendation should be submitted directly to Judy Fleming, Assoc. Director, TRP (Judith.fleming@childrens.harvard.edu). Of the three letters, one recommender must be from outside BCH. Please include a list of recommenders with contact information with application.