

Children's Hospital Boston

Translational Research Program

Application Instructions for the Translational Investigator Service:

Category: Mid-Career Investigator

Applications due March 13, 2012

Funding begins July 1, 2012

Overview of the Translational Investigator Service

The TIS is being 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 Children's Hospital Boston 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.

Rigorous review and selection of finalists will be done by members of the Clinical and Translational Research Executive Committee (CTREC). Finalists will be asked to participate in an "interview" with a panel of senior members of the CHB faculty. Following appointment to the TIS, investigators may solicit additional specific funding from CTREC for their specific research proposal.

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 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 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.

Eligibility

Individuals must be nominated by their departments. Multiple individuals can be nominated by each department. Applicant must be a member of the Children's Hospital Boston faculty. This award is suitable for mid-career investigators (rank of at least Assistant Professor for minimum of 3 years, but not yet Full Professor) who are interested in extending their research interests into the translational realm. An investigator holding a current K award or other mentored training grant would not be appropriate for the Mid-Career TIS program.

Review Criteria

- a. Excellence of the applicant as measured by prior publication history, experience in clinical or basic research or clinical expertise in specific diseases.
- b. Importance, creativity, comprehensiveness, and originality of Research Proposal. 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. Pertinent preliminary data that will strengthen the probability of success will be favorable considered.

- 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 where there is a focus on executing human trials using CHB-driven science and laboratory discoveries from this institution. Collaborations between basic researchers and clinicians at CHB 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 the department/division, patient, administrative and financial resources.
- e. Importance of proposed research to individual’s field.

Review Process

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

Details—Funding and Time Commitment

1. Funding will commence on July 1, 2012. 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 (salary plus 33% fringe) for 50% based on

a maximum total academic salary cap up to the NIH cap (currently \$179,700).

- b. There is an expectation that the applicant will develop NIH funding (e.g. R21, clinical R01's, PPG's and other programmatic or center grants) that can offset funding from the Translational Research Program in later years of the award.

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 CHB CRP (March or Sept).
- 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 presentations at a quarterly TIS mini-retreat)
- d. Regular participation and presentation at multi-institutional symposium such as the Harvard Catalyst colloquia series.

5. 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 distributions 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 CHB is expected).
- d. Updated list of current and pending funding.
- e. List of conferences attended and talks given in the past year.

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 #MidCareer). 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.
 - c. The gurarantee of protected time (minimum 50%) for the applicant to pursue his/her research endeavors.
3. Budget (1 year; use PHS 398 form) and Budget justification.
4. Research proposal – limit to 10 single-spaces pages, 12 point type.
5. Statement of how proposed research will be “translational” in scope, with a focus on the linkage between basic and clinical research (1 page).
6. Statement of career development plan and the impact this award would have (2 pages). Please address how prior training/education contributes to the likelihood of success as an independent translational researcher in the future.
7. Complete list of other sources of funding (both current and pending).
8. 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 should be from outside CHB. Please include a list of recommenders with contact information with application.