

Terms of Reference

2014 CST CNTRP Research Innovation Grant Competition

Background

The Canadian Society of Transplantation (CST) is a founding partner of the newly established Canadian National Transplant Research Program (CNTRP). The CST is an organization of professionals dedicated to leading, advancing, and advocating for patient care, research, and education in donation and transplantation in Canada. This partnership was established to support research and innovation under the CNTRP, advance the practice and science of transplantation, and specifically to support research fellowships for trainees affiliated with CNTRP. The ultimate goal of the partnership is to advance long-term health outcomes and quality of life for Canadian transplant recipients.

The CST will extend the existing partnership and provide operating grant funding for the Research Innovation Grants. This collaborative effort between the CST and the CNTRP is intended to seed new and innovative pilot projects in the transplant field. The CNTRP's New Initiatives Committee (NIC) will set guidelines for the competition, receive and process the applications, and peer-review, evaluate and rank the applications. The Canadian Liver Foundation, partner and supporter of the CNTRP, will provide financial administration for the research grant funds on behalf of the CNTRP and will disburse research funding to the selected Grant recipient(s).

Key Dates

Competition Launch	June 23, 2014
Application deadline	August 18, 2014
Notification Date	November 1, 2014
Funding Start Date	December 1, 2014
Study update submitted to NIC	Within 18 months of receipt of the Grant

Objectives and Scope

The objective of the CST CNTRP Research Innovation Grant competition is to support peer-reviewed pilot research project(s) that align with CNTRP's overall objective to increase organ and tissue donation in Canada and enhance the survival and quality of life of Canadians who receive transplants with the ultimate goal of improving patient care.

The primary area of focus for this competition is to nurture innovative research aligning with the strategic research priority of the CNTRP in the area of **translation of enhanced non-invasive diagnostics and monitoring into clinical practice**.

Non-invasive diagnostics and monitoring refers to the analysis of accessible body fluids, imaging studies or other techniques that are associated with minimal patient discomfort and are conducive to repeated or sequential assessment of the clinical status of the patient. Non-invasive techniques of interest are those that provide information that otherwise would require invasive procedures (e.g. biopsy), or that is currently not accessible with existing standard tests. These non-invasive techniques are most highly valued if they provide information in real-time on the status of the allograft or patient, and directly influence clinical decision-making.

In the setting of solid organ or bone marrow transplantation, the grants will support studies that test the feasibility, implementation or effectiveness of previously validated diagnostic or monitoring techniques in clinical practice. Funding will be restricted to techniques that are not considered as standard practice.

Grant recipients are expected to demonstrate improved understanding of the specific research area and/or contribute to improving patient care and integrate their proposed study within the existing CNTRP research structure.

Grants will be awarded to the successful applicant(s) (or applicant's institution on behalf of the applicant, if applicable). It is anticipated that 2 grants of \$25,000 CDN/each will be provided over an 18-month performance period.

Eligibility

The NIC shall receive and process applications and shall evaluate the submitted proposals. Proposals will be deemed eligible based on the following:

Eligible Applicants

The Principle Applicant must:

- Be an independent researcher working at a Canadian university or research institution
- Agree to integrate their study within the CNTRP structure if funded
- Must include an existing CNTRP member as a co-applicant on the submission if the Principle Application is not a current CNTRP member
- Be a Canadian resident
- Agree to sign a Research Grant Acceptance Letter with the Canadian Liver Foundation, who will provide financial administration for the CST CNTRP Research Innovation Grant.
- Agree to provide a progress report, including publication plan, to the CNTRP in dissemination of study results.

Eligible Research Proposals

In 2014, the research proposals being considered will be those addressing the area of translation of enhanced non-invasive diagnostics and monitoring into clinical practice, a strategic research priority within the CNTRP.

Preference will be given to new/pilot projects that have not been previously funded and where this funding could help the researcher become competitive for large/national level grant funding, or which support applications for public funding.

The study must be completed within 18 months of receipt of funding; no renewals will be considered. The proposed application should include a 'stand alone' project. The current Grant is not meant to complete funding for larger projects.

Applicants may submit multiple unique applications to any CNTRP Research Grant competition, however they can only accept one award from the CNTRP per year.

Non-eligible Research Proposals

The following types of proposals will not be eligible:

- Proposals for projects that have received funding from another source, including government or industry sponsors, will not be eligible to receive a CST CNTRP Grant unless said funding is shown by the applicant to be directed to a portion of the overall project/research that is separate and distinguishable from the portion to which the proposal relates.
- Proposal budgets in excess of \$25,000 CDN will not be considered unless there are available matching funds from the applicant's institution or other funding partner.
- Proposals that have already received a CNTRP sponsored research grant in the same year.

Review Criteria

All proposals will be reviewed and assessed by NIC.

Research proposals will be evaluated based on the following criteria:

Significance

- Scientific merit (validity, integrity, originality)
- Contribution to advancement of scientific knowledge in relevant therapeutic field
- Clinical relevance or potential clinical value and applicability

Feasibility

- Feasibility of study design, methodology, analysis
- Adequate power and sample size
- Study budget
- Proposed timelines

Integration

- How would the proposal be integrated with the CNTRP
- How would the project contribute to the mandate of the CNTRP

Guidelines for Application Submission

The research proposal should be novel, previously unpublished and not exceed 3 pages, with a maximum of 3 additional pages for figures or tables.

In addition to the 3 page proposal, the application must submit a half-page summary of the research proposal that highlights the hypotheses and objectives of the research proposal, the methodologies and the expected outcomes of the proposed research project. is required (Max ½ page). The applicant must attach a separate description of how the proposal will integrate and fit within the project and core structure of the CNTRP (Max ½ page) and the applicant must attach a lay abstract (max. 250 words) that can be used to explain the proposal to the general public. The applicant must also include a copy of their CIHR Academic Funding Common CV.

The completed application must be received by the NIC no later than **August 18, 2014**. The magnitude of the project should match the size of the award; the award is not intended to supplement a major grant, however it is anticipated that this funding will be used to produce data to apply for large/national level grant funding.

Documentation received after the submission deadline will not be submitted for review. The applicant is responsible for ensuring completeness of the application and incomplete applications will not be considered. Applicants may submit their application electronically to the CNTRP office.

The following are suggestions for preparation of the research proposal. The headings suggested include 1) Statement of Objective(s), 2) Recent relevant research by applicant, 3) Brief review of literature and background information, 4) Hypothesis(es), 5) Design and Methodology, 6) Integration with the CNTRP 7) Analysis of Data, 8) Anticipated Timeline, 9) Impact, Future research plans and Knowledge Translation, and 10) Budget.

In addition, the following must accompany the application: 1) Completed Application form, 2) Research proposal (Max 3 pages), 3) Half page Summary of the Research Proposal, 4) a description of how the proposal will integrate and fit within the project and core structure of the CNTRP (Max 1 page), 5) a lay abstract (max. 250 words) that can be used to explain the proposal to the general public, and 6) the Principal Applicant's CIHR Common Funding CV. Incomplete and unsigned applications will be disqualified. Applicants may also include letters of support and/or commitment from the Chair of the Department/Division indicating the level of institutional and/or university support.

The applicant must use Times New Roman or Arial font, size 11 points or larger. Use at least 0.75 inch margins (top, bottom, left, and right) for all pages. The section name and the name of the Principal Applicant should appear in the header.

Conditions of the CST CNTRP Research Innovation Grant

Research Ethics Board approval:

The successful applicant must provide evidence of appropriate Ethics Committee approval along with consent forms where human subjects are involved in the study before the funding is released.

Financial Considerations

The amount of each Grant should include direct costs (labour and study costs), study drug costs (if applicable), and indirect costs (publication, and software license fees).

Research Grant Administration

A copy of the Template Grant Agreement, signed by the Grant recipient and the Grant recipient's affiliated institution (if applicable) must be returned to the CNTRP prior to disbursement of Grant funds. Upon review and approval of the signed Template Grant Agreement, the CNTRP will authorize the Canadian Liver Foundation to issue a Research Grant Acceptance Letter to initiate disbursement of research grant funds for the CST CNTRP Research Innovation Grant. Studies must be designed to be completed within 18 months after receipt of funding, yielding results that would merit submission as an abstract to a scientific meeting and subsequent publication in a peer-reviewed journal.

Progress Reports

The Grant recipient must provide a progress report to the CNTRP within 18 months of receipt of the Grant summarizing work completed, including any publications, as well as, an accounting for funds which will be shared with the CST.

Publications

Grant recipients are expected to present their findings at scientific meetings, including the CNTRP Annual Scientific Meeting, and to submit their work for publication in peer-reviewed journals. NIC shall require a copy of all proposed publications upon submission for publication or other public disclosure and NIC shall provide said information to the CST forthwith. All publications that result from a project supported by the CST CNTRP Grant should carry the following acknowledgement: "This research was supported by the *CST CNTRP Research Innovation Grant* funded by the Canadian Society of Transplantation and jointly established by the Canadian Society of Transplantation and the Canadian National Transplant Research Program."

Grant Recipient Responsibilities

The following responsibilities must be assumed and carried out by the Grant recipient:

- Study contract review and execution
- Become a member of the CNTRP (if not already a member) and comply with any of the current CNTRP investigator responsibilities
- Research Ethics Board submission and approval (if applicable)
- Health Canada Clinical Trial Application (CTA) submission and approval (if applicable)
- Ensure study conduct according to all applicable regulations or guidelines (e.g. ICH-GCP, etc.)
- Study-related activities such as data management, statistical analysis, medical writing, monitoring, etc.
- Registration and posting of study results on <http://prsinfo.clinicaltrials.gov>
- Safety Reporting to Health Canada, the research ethics board (as per local requirements), and if a drug product is involved, the Product Safety/Pharmacovigilance group for the appropriate company. Please refer to the Serious Adverse Events and Lack of Therapeutic Efficacy Reporting Section.
- Communication of progress updates to the NIC
- Integration of the study into the CNTRP structure
- Forward copy of abstract(s)/manuscripts(s) to the NIC upon submission to congress/journal

Serious Adverse Events (SAE) and Lack of Therapeutic Efficacy

1. As sponsor of the study, the grant recipient is responsible for reporting SAEs and Lack of Therapeutic Efficacy directly to **Health Canada** (pursuant to the Canadian *Food and Drug Regulations*) and to the local REB, as required.
2. If a drug product is involved, the Grant recipient is also required to notify the Product Safety/Pharmacovigilance group for the appropriate company.

A **Serious Adverse Event** is any untoward adverse event/adverse drug reaction that at any dose, results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/ incapacity, is a congenital anomaly/birth defect, or results in other medically important events.

Lack of Therapeutic Efficacy – If a health product fails to produce the expected intended effect, there may be an adverse outcome for the patient, including an exacerbation of the condition for which the health product is being used. Clinical judgment should be exercised by a qualified health care professional to determine if the problem reported is related to the product itself, rather than one of treatment selection or disease progression since health products cannot be expected to be effective in 100% of the patients.

Notification of Decision for the CST CNTRP Research Innovation Grant Competition

Grant recipients will be notified of the decision regarding funding around November 1, 2014. Both successful and unsuccessful applicants will receive a summary and a constructive critique from the NIC.

Address for Submissions

Please send completed submissions, no later than August 18, 2014 to:

Attention:

David Hartell
Operations and Program Manager
Canadian National Transplant Research Program
davidhartell@cntrp.ca