Terms of Reference

2015 CNTRP Astellas Research Innovation Grant Competition

UPDATED June 29, 2015

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Background

In November 2012, Astellas Pharma Canada, Inc. ("Astellas") established a partnership with the Canadian National Transplant Research Program (CNTRP). This partnership resulted in a 5- year funding commitment from Astellas to support CNTRP research and innovation in addressing barriers within the field of transplant, with the ultimate goal of advancing long-term health outcomes and quality of life for Canadian transplant patients.

Enhancing Astellas's sustained commitment to research and development within the transplant scientific community is the continuation of the CNTRP Astellas Research Innovation Grant Competition. This collaborative effort between Astellas and the CNTRP is intended to seed new and innovative pilot projects in the transplant field. Astellas will provide the funding for the Grants. The CNTRP's New Initiatives Committee (NIC) will set guidelines for the competition, receive and process the applications, and 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).

In June 2015, the Alberta Transplant Institute (ATI) at the University of Alberta joined this competition to provide additional funding to support Alberta researchers participating in this competition to bring their new and innovative pilot projects into the CNTRP. Grants funded with this additional funding will be recognized as a "CNTRP ATI Innovation Grant".

In July 2015, the Multi-Organ Transplant Program at the University Health Network (UHN) joined this competition to provide additional funding to support UHN researchers participating in this competition to bring their new and innovative pilot projects into the CNTRP. Grants funded with this additional funding will be recognized as a "CNTRP UHN Innovation Grant".

Key Dates

Competition Launch	**May 4th, 2015**
Application deadline	**August 18th, 2015**
Notification Date	**October 6th, 2015**

Funding Start Date	**December 1st, 2015**
Study update submitted to NIC	**Within 18 months of receipt of the Grant**

Objectives and Scope

The objective of the CNTRP Astellas 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 **personalized medicine approaches in transplantation to improve health outcomes.**

Personalized medicine refers to the customization of healthcare - with medical decisions, practices, and/or products being tailored to the individual patient in regard to the prevention, diagnosis, or treatment of disease. In this model, diagnostic testing (including genetic testing) is often employed for selecting appropriate treatments, management strategies or customized therapeutic products. Personalized medicine is expected to result in improved health outcomes by rationalizing diagnostic and treatment approaches tailored to address specific risk profiles of a restricted patient population. The applicant is expected to define how their approach will directly improve health outcomes, and how this applies to affecting the long-term outcome for patients.

In the setting of solid organ or bone marrow transplantation, the grants will support evaluation of personalized medicine interventions or strategies with the aim of translating them into clinical practice. These approaches should be applicable to the clinical setting today and be expected to result in both improved health outcomes in a restricted (at-risk) target population and cost/benefit associated with their selectivity. This may include identification of patient characteristics that confer a significantly different risk profile to a restricted patient population, with implementation of strategies to modify the risk and/or determination of the cost/benefit associated with similar tailored interventions.

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 **3 grants of $25,000 CDN/each** will be provided by the CNTRP Astellas Research Innovation Grant competition over an 18-month performance period.

The Alberta Transplant Institute will provide an additional grant of $25,000 CDN to the top ranked Alberta based researcher through the CNTRP ATI Research Innovation Grant competition over an 18-month performance period.

The Multi-Organ Transplant Program at the University Health Network will provide an additional grant of $25,000 CDN to the top ranked unfunded UHN researcher through the CNTRP UNH Research Innovation Grant competition 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
- Be a Canadian resident, and conduct the research at a Canadian institution (study subjects may be enrolled from other countries)
- Agree to integrate their study within the CNTRP structure if funded and agree to become a participating CNTRP member
- Must include an existing CNTRP member as a co-applicant on the submission if the Principle Application is not a current CNTRP member
- Agree to sign a Research Grant Acceptance Letter with the Canadian National Transplant Research Program who, in partnership with the Canadian Liver Foundation, will provide financial administration for the CNTRP Astellas Research Innovation Grant
- Agree to provide a progress report, including publication plan, to the CNTRP in dissemination of study results
- If successful, agree to have their application shared in confidence with Astellas for internal documentation and auditing purposes

Additional Eligibility Criteria for Alberta Applicants:

In addition to the eligibility criteria listed above, the Principle Applicant must:

- Be an independent researcher working at a University or research institution in Alberta
- Be a Canadian resident, and conduct the research at an Alberta institution (study subjects may be enrolled from other provinces/countries)
- Agree to integrate their study within the CNTRP structure if funded and agree to become a participating CNTRP and ATI member
- Agree to sign a Research Grant Acceptance Letter with the Canadian National Transplant Research Program who, in partnership with the Alberta Transplant Institute, will provide financial administration for the CNTRP ATI Research Innovation Grant
- If successful, agree to have their application shared in confidence with ATI for internal documentation purposes

Additional Eligibility Criteria for UHN Applicants:

In addition to the eligibility criteria listed above, the Principle Applicant must:

- Be an independent researcher that is a member of the Multi-Organ Transplant Program of the University Health Network
- Be a Canadian resident, and conduct the research at a UHN institution (study subjects may be enrolled from other provinces/countries)
- Agree to sign a Research Grant Acceptance Letter with the Canadian National Transplant Research Program who, in partnership with the MOT UHN, will provide financial administration for the CNTRP UNH Research Innovation Grant
- If successful, agree to have their application shared in confidence with the UHN MOT for internal documentation purposes

Eligible Research Proposals

In 2015, the research proposals being considered will be those addressing the area of **personalized medicine approaches in transplantation to improve health outcomes,** 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. Successful applicants from the 2014 CNTRP Research Innovation Grant competitions will not be considered for this competition.

The research proposal may belong to one of the following categories:

- Clinical, translational, interventional studies
- Basic research, genetic studies
- Epidemiology, health outcomes, and quality of life studies

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. Principle applicants that received a CNTRP Research Grant in 2014 will not be considered for the 2015 competition.

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 CNTRP Astellas 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.
- Proposals for pharmaceutical product development (including studies on non-approved indications for drugs) and/or product comparison, or product promotion will not be considered.
- Research proposals that have already received funding from a CNTRP sponsored research grant will not be considered.
- Grant funds should not be used as matching funding for a CNTRP training grant, and should not be used for clinical training.

Review Criteria

All proposals will be reviewed by the NIC to ensure relevance to the terms of the competition. Relevant 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 and how does it fit with the specified CNTRP Project or Core
- 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 (not including references), with a maximum of 3 additional pages for figures or tables.

In additional to the 3 page proposal, the application must:

- Submit a half-page summary of the research proposal that highlights how the research proposal addresses the theme of **personalized medicine approaches in transplantation to improve health outcomes** (Max ½ page);
- Attach a separate description of how the proposal will integrate and fit within a specific project or core of the CNTRP (Max ½ page), and provide a letter of support from the lead of that Project/Core (www.cntrp.ca/research);
- Attach a lay abstract (max. 250 words) that can be used to explain the proposal to the general public;
- Include a copy of their CIHR Academic Funding Common CV.
- 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 completed application must be received by the NIC no later than **11:59pm PDT on August 18, 2015**. 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 and unsigned 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.

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 CNTRP Astellas Research Innovation Grant,

the CNTRP ATI Research Innovation Grant & the CNTRP UNH 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). Institutions are expected to waive overhead fees that might otherwise apply to industry-funded research and funding cannot be used to support institutional overhead costs.

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 and receipt of evidence of ethics committee approval, the CNTRP will authorize the Canadian Liver Foundation to issue a Research Grant Acceptance Letter to initiate disbursement of research grant funds for the CNTRP Astellas Research Innovation Grant. The CNTRP ATI Grant recipient will receive their funding directly from the ATI and the CNTRP UNH Grant recipient will receive their funding directly from the MOT UHN.
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.

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. The NIC shall require a copy of all proposed publications upon submission for publication or other public disclosure and the NIC shall provide said information to Astellas, ATI or UHN MOT forthwith.

All publications that result from a project supported by the CNTRP Astellas Grant should carry the following acknowledgement: "This research was supported by the *CNTRP Astellas Research Innovation Grant* funded by Astellas Pharma Canada, Inc. and jointly established by Astellas Pharma Canada, Inc. and the Canadian National Transplant Research Program."

All publications that result from a project supported by the CNTRP ATI Grant should carry the following acknowledgement: "This research was supported by the *CNTRP ATI Research Innovation Grant* funded by the Alberta Transplant Institute and jointly established by the Alberta Transplant Institute and the Canadian National Transplant Research Program."

All publications that result from a project supported by the CNTRP UNH Grant should carry the following acknowledgement: "This research was supported by the *CNTRP UNH Research Innovation Grant* funded by the Multi-Organ Transplant Program at the University Health Network and jointly established with 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

Additional Grant Recipient Responsibilities for the CNTRP ATI Competition:

The following responsibilities must be assumed and carried out by the Grant recipient of the CNTRP ATI Grant Competition:

- Become a member of the Alberta Transplant Institute (if not already a member) and comply with any of the current ATI investigator responsibilities
- Forward a copy of abstract(s)/manuscripts(s) to the ATI upon submission to congress/journal

Additional Grant Recipient Responsibilities for the CNTRP UNH Competition:

The following responsibilities must be assumed and carried out by the Grant recipient of the CNTRP UHN Grant Competition:

- Forward a copy of abstract(s)/manuscripts(s) to the MOT UHN 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.[1]

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 CNTRP Astellas Research Innovation Grant Competition

Grant recipients will be notified of the decision regarding funding in October 2015. 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, 2015 to:

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

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[1] If the research involves a drug product marketed by Astellas Pharma Canada, Inc., the Grant recipient is required to notify **Astellas Pharma Global Development – Product Safety & Pharmacovigilance (PSP)** at fax: 1-847-317-1241 or Email: Safety-us@astellas.com within twenty-four (24) hours of receiving a SAE or Lack of Therapeutic Efficacy report.

Also Required to be Collected by the Independent Investigator

Product Safety Information ***("PSI")*** including but not necessarily limited to:

1. *Death (always considered serious)*
2. Abuse/Misuse/Overdose
3. Medication Errors (in prescribing, dispensing, or administration)
4. Drug Exposure during impregnation, pregnancy, breastfeeding or as a result of one's occupation
5. AEs reported in association with suspected or confirmed quality defects or counterfeit reports
6. Suspected transmission of an infectious agent