2015/2016 Astellas CST Clinical Research Grant Terms of Reference

I. Table of Contents

II. Background

Astellas Pharma Canada, Inc. ("Astellas") is enhancing their ongoing commitment to research and development within the transplant community through a collaboration with the Canadian Society of Transplant to introduce the *2015/2016 Astellas CST Clinical Research Grant Program*. This new commitment aims to support investigator-sponsored research in the transplant field, with recipients subject to internal peer review. Astellas will provide the funding for the Program. The CST will provide the receipt, processing, evaluation, and decision-making infrastructure for the Program and will administer the funds and enter into investigator-sponsored study agreements with the selected Grant recipient(s).

III. Key Dates

Competition Launch	October 9, 2015
Application deadline	January 31, 2016
Notification	March 31, 2016
Funding Commencement	July 1, 2016
Study update submitted to CST	12 months after receipt of funding

IV. Objectives and Scope

The objective of the Astellas CST Clinical Research Grant Program is to support peer-reviewed research that addresses barriers in the field of transplantation, with the ultimate goal of advancing long-term health outcomes and quality of life for Canadian transplant patients.

The primary focus of the Program is to support a clinical research project related to solid organ transplantation.

Grant recipients are expected to demonstrate that their proposed research will improve knowledge in a scientific area relevant to organ donation or transplantation and/or contribute to improving patient care. Grants will be awarded to the successful applicant(s). It is anticipated that 1 grant of $100,000 will be awarded in July 2016 with staggered disbursement over a two year period.

V. Eligibility

The CST Research Committee and Grants and Awards Committee will together receive and process applications and shall evaluate the submitted proposals. Proposals will be deemed

eligible based on the following:

A. Eligible Applicants

The successful Principal applicant must be a:

- A Canadian citizen or landed immigrant;
- A CST Member in good standing
- A mid-career researcher ≥ at least 5 years after their first university appointment, but not yet attained the rank of Full Professor as of July 1 of the year of the award
- If successful, agree to have their application shared in confidence with Astellas for internal documentation and auditing purposes.
- Agree to provide a progress report, including publication plan, to the CST for dissemination of study results.

B. Eligible Research Proposals

In 2015/2016, the research proposals being considered will be those addressing the broad area of clinical research or translational research related to solid organ transplantation. Bench research will not be considered. Clinical research involves the scientific investigation of the etiology, prevention, diagnosis, or treatment of human disease using human subjects, human populations or materials of human origin. Patient level research data must be part of the core project.

C. Non-eligible Research Proposals

Any research that does not directly involve information or materials from humans (e.g., mouse models of human disease) and, in the judgment of the selection committee, does not fulfill the definition of clinical research above, will not be considered.

D. Review Criteria

All proposals will be reviewed and assessed by March 31, 2016 with the final approval of the successful candidate by the CST Board.

Research proposals will be evaluated based on the following criteria:

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

2. *Feasibility*
   - Feasibility of study design, methodology, analysis
   - Adequate power and sample size

- Study Budget
- Proposed timeline

3. *Support*
   - A letter of support and/or commitment from the Chair of the Department/Division indicating the level of institutional and/or university support.

A small number of highly-ranked applicants may be invited to a webinar and/or in-person presentation of their research proposal to a panel made of 4-5 CST Research Committee members. The panel will then ask questions in order to determine the successful applicant.

VI. Guidelines for Application Submission

The complete proposal, together with all attachments, must be submitted as a single pdf file named as the author's last name. Research proposal should be novel, previously unpublished and not exceed 7 pages, with a maximum of 5 additional pages for references, figures, or tables.

The completed application must be received by the *CST* no later than *11:59 pm CT*, *January 31, 2016*. 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 competitively 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 should submit their application electronically to *admin@cst-transplant.ca* , *with* the cover letter addressed to:

CST Research and Grants and Awards Committees
114 Cheyenne Way,
Ottawa, Ontario
K2J 0E9

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) Statistical Analysis, 7) Anticipated Timeline, 8) Impact, Future Research Plans and Knowledge Translation, and 9) Budget.

In addition, the following must be included with the application: 1) Completed Application form, 2) Research proposal (Max 7 pages), 3) the Principal Applicant's CIHR Common Funding CV, 4) Co-Applicants' CIHR Common Funding CV. Applicants may also include a letter 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.

VII. Conditions of the Astellas CST Clinical Research Grant

A. 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.

B. Financial Considerations

The amount of each Grant is intended to cover all costs associated with the study, including all 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.

C. Research Grant Administration

1. Progress Reports

The Grant recipient must provide a progress report to the CST within 12 months of receipt of the Grant summarizing work completed, including any publications and an accounting for funds.

2. Publications

Grant recipients are expected to present their findings at scientific meetings and/or to submit their work for publication in peer-reviewed journals. The CST shall require a copy of all proposed publications upon submission for publication or other public disclosure and shall provide the said information to Astellas forthwith. All publications and presentations that result from a project supported by the Astellas CST Clinical Research Grant should carry the following acknowledgement: "*This research was supported by the Astellas CST Clinical Research Grant provided by Astellas Pharma Canada, Inc. and jointly established by Astellas Pharma Canada, Inc. and the Canadian Society of Transplantation.*"

D. Grant Recipient Responsibilities

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

- Review and execution of CST study grant agreement
- Research Ethics Board submission and approval (if applicable)
- Health Canada Clinical Trial Application (CTA) submission and approval (if applicable)

- Compliance with all applicable laws, 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 CST
- Forward copy of abstract(s)/manuscripts(s) to the CST upon submission to congress/journal

VIII. Notification of Decision for the Astellas CST Clinical Research Grant

Grant recipients will be notified of the decision regarding funding around March 31, 2016. Both successful and unsuccessful applicants will receive a summary and a constructive critique from the CST.

IX. Serious Adverse Events (SAE) and Lack of Therapeutic Efficacy

1. 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

[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 – Global Pharmacovigilance (GPV)** 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 or any of the Product Safety Information as listed below.

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

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.