



2018 CST - CNTRP Basic Research Catalyst Grant Terms of Reference

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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 (CST) and the Canadian National Transplant Research Program (CNTRP) to introduce the *2018 CST-CNTRP Basic Research Catalyst Grant Program*. This 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 infrastructure for processing and evaluation of applications to the Program, and will administer the funds and enter into investigator-sponsored study agreements with the selected Grant recipient(s). The CNTRP will offer successful applicants access to CNTRP infrastructure and resources which may include: researcher interaction/networking, grant support, training, patient partnership, access to CNTRP annual meeting, and resources to support future grant development. The competition is open to CST and CNTRP members.

III. Key Dates

Competition Launch	March 1, 2018
Letter of Intent (LOI) Deadline	May 21, 2018
Application deadline for invited full applications	July 30, 2018
Notification of two finalists for presentation at Canadian Transplant Summit	September 15, 2018
Presentation at the 2018 Canadian Transplant Summit	October 16, 2018
Funding Start date	January 1, 2019
Study update submitted to CST	12 months after receipt of funding

IV. Objectives and Scope

The objective of the CST-CNTRP Basic Research Catalyst Grant Program is to support peer-reviewed research that addresses questions of relevance to 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 impactful research projects related to solid organ transplantation. Grant competitions in the past 2 years targeted clinical

research and clinical innovation; therefore, this year the focus will be basic science.

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 and outcome. Grants will be awarded to the successful applicant(s). It is anticipated that 2 grants of minimum \$40,000 will be awarded in 2018 with disbursement in 2019. An additional \$10,000 will be awarded at the Canadian Transplant Summit competition to the applicant whose presented proposal ranks most highly by the judging panel. A further \$10,000 will be awarded to the applicant whose presented proposal ranks most highly by audience vote at the Canadian Transplant Summit competition. Therefore, the maximum possible award is \$60,000.

V. Eligibility and Review Criteria

The CST Research Committee and Grants and Awards Committee, together with the CNTRP, will form the “Review Panel”(also see section “Review Process” below). CST will receive and process applications and the joint CST-CNTRP Review Panel will evaluate the research proposals. Proposals will be deemed eligible based on the following:

Eligible Applicants

The successful Principal applicant must be a:

- A Canadian citizen or landed immigrant;
- A CST and/or CNTRP member in good standing;
- Non-past recipient of the Astellas CST Clinical Research Grant Competition or the CNTRP-Astellas Research Innovation Grant (Primary Investigator or Co-Investigator) within the last three years.
- An early or mid-career researcher not >10 years after their first university appointment, and 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 and CNTRP for dissemination of study results.
- Agree to enter into an investigator-sponsored study agreement with CST.

Eligible Research Proposals

In 2018, the research proposals being considered will be those addressing the broad area of basic research or translational research related to solid organ transplantation. Basic

research refers to systematic study directed toward greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts without necessarily having specific applications in mind.

This goal of this grant is to catalyze new ideas and projects to allow preliminary data to be generated in support of future applications for larger grant applications.

Proposals intended to supplement an existing / already approved major grant are NOT eligible and will not be reviewed. It is anticipated that this funding will be used to produce data to competitively apply for large/national level grant funding.

Investigators may only submit ONE proposal as Principal Investigator.

Non-eligible Research Proposals

Any research that does not directly affect the the field of transplantation and, in the judgment of the selection committee, does not fulfill the definition of basic research above, will not be considered.

Letter of Intent

Applicants will be required to submit a 1-page letter of intent including the study title and outline of study objectives and methods by the stated deadline. Detail should be sufficient to confirm that the proposal will meet eligibility criteria. This will allow a sufficiently qualified review panel to be assembled.

Review Criteria

Research proposals will be evaluated based on the following criteria:

Significance

- Scientific merit (validity, integrity, originality)
- Novelty of potential discovery and research approach
- Contribution to advancement of scientific knowledge in transplantation
- Potential to develop into a larger project, fundable in a national competition

Feasibility

- Feasibility of study design, methodology, analysis
- Adequately justified power and sample size, aligned with the goals of the project
- Study Budget. Applicants are expected to plan for a \$40,000 base budget. It

should be clear to reviewers that the applicant will have sufficient funds to carry out the project.

- Proposed timeline
- Realistic plan for next steps

Support

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

Review Process:

Each application will be independently reviewed and scored by a minimum of two reviewers using the above review criteria. Individuals who are a principal investigator or a co-investigator on a submitted application will be excluded from the review process. After all applications have been reviewed, a Review Panel Teleconference will take place for discussion. During the teleconference, the 1st reviewer will be asked to provide a brief summary of the applicant/application followed by an assessment of the strengths and weaknesses. The 2nd reviewer will add comments if any and share their evaluation (strengths/weaknesses), followed by a discussion on the consensus score. At the end of the discussion, each Review Panel Member will be required to provide a score within +/- 0.5 of the consensus score from which the mean score will be calculated. Applications are then ranked according to the mean score. If necessary, in the event of a tie, further discussions and a 2nd round of scoring by the Review Panel Members will occur to determine the successful applications.

From all applications, two will be selected to present their project in the final competition at the 2018 Canadian Transplant Summit, on October 16, 2018 in Ottawa. Both of those selected to present will receive a \$40,000 award. An additional \$20,000 in funding will be awarded at the Canadian Transplant Summit. \$10,000 will be awarded based on the judges' decision (judging panel to be composed of the 3 CST members plus 4 anonymous members of the Review Panel) and \$10,000 will be awarded based on audience vote (people's choice). It is possible that the same applicant will receive both the judges' choice and the people's choice and therefore receive \$60,000. Alternatively, each of the presenters may receive \$10,000, such that each receives \$50,000.

The finalists must be present at the 2018 Canadian Transplant Summit on October 16, 2018, in Ottawa to receive one of the two awards in the Competition. Each finalist will have twenty (20) minutes to present, with fifteen (15) minutes for presentation and five (5) minutes to respond to questions from the judges and audience. The goal of the presentation is for applicants to explain their research proposal in a way that is

accessible to the general scientific audience and explain how their project would be enhanced by an additional \$10,000 to \$20,000. The question they will have to address is what could they add to the project with the additional funding that would increase its impact and/or increase their ability to scale it up. Judges and the audience will be asked to rank the presentations based on scientific merit (impact, novelty, methodology), feasibility, and clarity.

The process for ranking/voting will be communicated to the audience at the meeting. The winners will be announced at the meeting, shortly after the judges' and audience votes have been tallied.

The finalists are required to pay for their own travel/accomodation/registration to attend the Canadian Transplant Summit.

By accepting an award, a finalist agrees that CST, CNTRP, Astellas and their respective affiliates and agencies may use of his or her name and/or likeness for advertising and promotional purposes of the Competition without additional compensation.

VI. Guidelines for Application Submission

The 1-page letter of intent must be submitted through the online submission form <http://www.cst-transplant.ca/awards-and-grants.html> and needs to include the following:

- 1) Applicant names (principal and co-applicants)
- 2) Provisional title
- 3) Outline of study objectives and planned methods.

NOTE: All grant applications must submit a Letter of Intention by the LOI deadline date. Any grant applications received that do not have a submitted LOI will be deemed ineligible.

The complete proposal, together with all attachments, must be submitted as a **single pdf file** named as the author's last name. Research proposals should be novel, and not exceed 7 pages, with a maximum of 5 additional pages for references, figures, or tables and a maximum of 3 pages for budget and budget justification.

The completed application must be received by the CST no later than 11:59 pm ET, June 30, 2018. The scope of the project should match the size of the award.

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 complete 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. It is not necessary to adhere strictly to these suggestions. The headings suggested include:

- 1) Statement of Objective(s) and Hypothesis(es)
- 2) Brief review of literature and background information
- 3) Recent relevant research by applicant
- 4) Design and Methodology
- 5) Statistical Analysis
- 6) Anticipated Timeline
- 7) Impact, Future Research Plans

Budget and justification (3 pages maximum)

The complete application package must include the following:

- 1) Completed Application form,
- 2) Research proposal (Max 7 pages),
- 3) the Principal Applicant's Common CV CHIR - Academic format. 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.
- 4) Co-applicants' Common CVs- CIHR Co-applicant format
- 5) Budget and budget justification (max 3 pages)
- 6) Appendix (tables and figures; max 5 pages)

The applicant must use Times New Roman font, size 11 points or larger. Use at least 0.75 inch margins (top, bottom, left, and right) and single line space for all pages. Proposals that do not meet these specifications will not be reviewed. The section name and the name of the Principal Applicant should appear in the header.

VII. Conditions of the CST-CNTRP Research Grant

Research Ethics Board and Animal Health approval

The successful applicant must provide evidence of appropriate Ethics Committee and/or Animal Health 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 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.

Research Grant Administration

Progress Reports

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

Publications

Grant recipients are expected to present their findings at scientific meetings (including CST and CNTRP annual 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 CST CNTRP Clinical Research Grant should carry the following acknowledgement: *“This research was supported by the CST-CNTRP Basic Research Catalyst Grant provided by Astellas Pharma Canada, Inc. and jointly established by Astellas Pharma Canada, Inc., 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:

- Review and execution of study grant agreement
- Research Ethics Board submission and approval (if applicable)
- Animal Health 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 and CNTRP
- Forward copy of abstract(s)/manuscripts(s) to the CST and CNTRP upon submission to congress/journal