



The Canadian **DONATION** and
TRANSPLANTATION Research Program

Programme de recherche en **DON**
et **TRANSPLANTATION** du Canada

CDTRP Research Innovation Grant Competition - 2019

BACKGROUND

Since 2012, the Canadian Donation and Transplantation Research Program (CDTRP) has supported research and innovation that addresses barriers within the fields of donation and transplantation, with the ultimate goal of advancing long-term health outcomes and quality of life for Canadian transplant patients.

Through strategic partnerships with several key partners across Canada, the CDTRP has sustained a commitment to research and development within the transplant scientific community through the continued launch of the CDTRP Research Innovation Grant Competitions. This collaborative effort between the CDTRP and our partners is intended to seed new and innovative pilot projects in the transplant and donation field.

For the 2019 competition, **CDTRP** is proud to partner with the following organizations to provide funding to support up to 14 grants:

- the **Addison Fund / Transplant Research Foundation of British Columbia** (TRFBC),
- **Canadian Liver Foundation** (CLF),
- **Cystic Fibrosis Canada** (CF Canada),
- **Kidney Foundation of Canada** (KFOC),
- **Paladin Labs Inc.** (Paladin)
- **SickKids Transplant & Regenerative Medicine Centre** (SickKids)
- **Université de Montréal** (UdeM)
- **University Health Network Multi-Organ Transplant Program** (UHN-MOT),

The CDTRP's New Initiatives Committee (NIC) has developed the guidelines for the competition, will receive and process the applications, and will evaluate and rank the applications through a competitive peer reviewed process.

KEY DATES

Competition Launch: November 20, 2019

Application Deadline: February 19, 2020

Notification Date: May 7, 2020

Funding Start Date: May 20, 2020, or upon confirmation of REB approval

Study update submitted to NIC: Within 18-24 months of Funding Start Date

OBJECTIVES AND SCOPE

The primary objective of the CDTRP Research Innovation Grant competition is to support new peer-reviewed pilot research projects that align with CDTRP's One-Transplant-for-Life vision, which is to ***fulfill every donor opportunity*** and ***turn transplant into a cure***. These projects must be new stand-alone studies that **align with one of the 5 Themes** of the CDTRP and should be used to generate preliminary data to support further investigation. The 5 CDTRP Themes are:

1. Create a culture of donation
2. Inform universal practices for donation
3. Engineer and allocate a better graft
4. Tailor an optimal immune system for each patient
5. Restore long-term health

Grant recipients are expected to integrate their proposed study within the CDTRP research structure.

The total value of the competition is \$450,000 and each grant is worth a total of \$30,000 CDN, enough to support 15 grants (pending availability of partner funding).

Of the \$450,000, we will support grants in the following strategic areas:

- **4 grants of \$30,000 CDN/each** to support new research that addresses the One-Transplant-for-Life vision and aligns with one of the 5 Themes. These will be provided through the CDTRP Research Innovation Grant competition over an 18-24 month performance period with funding provided by the Canadian Donation and Transplantation Research Program.
- **2 grants of \$30,000 CDN/each** to support new research that addresses the One-Transplant-for-Life vision and aligns with one of the 5 Themes. These will be provided through the CDTRP Research Innovation Grant competition over an 18-24 month performance period with funding provided by the Paladin Labs Inc.
- **2 grants of \$30,000 CDN/each** to support new research related to ***kidney donation and/or transplantation*** that addresses the One-Transplant-for-Life vision and aligns with one of the 5 Themes. These will be provided through the CDTRP KFOC Research Innovation Grant competition over an 18-24 month performance period with funding provided by the Kidney Foundation of Canada.
- **1 grant of \$30,000 CDN/each** to support new research related to ***liver donation and/or transplantation*** that addresses the One-Transplant-for-Life vision and aligns with one of the 5 Themes. These will be provided through the CDTRP CLF Research Innovation Grant competition over an 18-24 month performance period with funding provided by the Canadian Liver Foundation.
- **1 grant of \$30,000 CDN** to support new research in ***lung transplantation that addresses the unique needs of the cystic fibrosis community***, including: improving long-term health outcomes for cystic fibrosis transplant recipients; transplant immunology and infection in cystic fibrosis; and addressing post-transplant health and social challenges for those living with cystic fibrosis (e.g. long-term exposure to high doses of anti-rejection medications, mental health, support with respect to social re-integration). This

will be provided through the CDTRP CF Canada Research Innovation Grant competition over an 18-24 month performance period with funding provided by Cystic Fibrosis Canada.

- **1 grant of \$30,000 CDN/each** to support new research related to **pediatric solid organ transplantation** that addresses the One-Transplant-for-Life vision and aligns with one of the 5 Themes. This Principal Applicant on the project must be based in **British Columbia**, however the study can involve other sites and patients from across the country. This will be provided through the CDTRP Addison Fund Research Innovation Grant competition over an 18-24 month performance period with funding provided by the Addison Fund / Transplant Research Foundation of British Columbia.
- The SickKids Transplant & Regenerative Medicine Centre will provide **1 additional grant of \$30,000 CDN/each** to the top ranked **unfunded SickKids researcher** through the CDTRP SickKids Research Innovation Grant competition over an 18-24 month performance period
- The Université de Montréal will provide **1 additional grant of \$30,000 CDN/each** to the top ranked **unfunded UdeM researcher** through the CDTRP UdeM Research Innovation Grant competition over an 18-24 month performance period
- The UHN-MOT will provide **2 additional grants of \$30,000 CDN/each** to the top ranked **unfunded UHN researchers** through the CDTRP UHN Research Innovation Grant competition over an 18-24 month performance period.

Each grant will be awarded to the successful applicant(s) via the Primary Applicant's institution.

ELIGIBILITY AND RELEVANCE

The NIC shall receive and process applications and shall evaluate the submitted proposals for both relevance and eligibility to the competition prior to peer review. Proposals will be deemed eligible and relevant 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)
- Include an existing CDTRP Investigator as a co-applicant on the submission if the Principal Applicant is not a current CDTRP Investigator (see list of CDTRP Investigators: www.cntrp.ca/investigators-and-associate-members)
- Agree to integrate their study within the CDTRP structure if funded and agree to become a participating CDTRP Investigator
- Agree to sign a Research Grant Acceptance Form with the CDTRP
- Agree to provide progress reports, including publication plan, to the CDTRP in dissemination of study results

- Agree to publish their work on behalf of the CDTRP and list the CDTRP as one of their author affiliations
- Agree to acknowledge the CDTRP and relevant partner funding on any related publications arising from the study
- If successful, agree to have their application shared in confidence with the relevant funding partner for internal documentation and auditing purposes
- Agree that any partner funder may disclose the amount and nature of the Grant publicly on its website and in connection with any other public disclosure of payments/funding to healthcare professionals and healthcare organizations

Eligible Research Proposals

In 2019, the research proposals being considered will be those that address **the *One-Transplant-for-Life* vision – fulfilling every donor opportunity and turning transplantation into a cure.**

This funding is intended to support 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. The research proposal must **align with one of the 5 Themes** of the CDTRP.

The proposed application should describe a ‘stand alone’ project. The grant is not meant to complete funding for larger projects. The study must be completed within 24 months of receipt of funding; no renewals or extensions beyond 24 months will be considered.

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 CDTRP Research Innovation 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 \$30,000 CDN will not be considered unless there are **confirmed** leveraged funds from another source.
- Proposals for pharmaceutical product development (including studies on non-approved indications for drugs) and/or product comparison, or product promotion will not be considered.
- Successful applicants from the 2018 CNTRP Research Innovation Grant competition will not be considered for this competition. Applicants may submit multiple unique applications to the CDTRP Research Innovation Grant competition; however, only one award can be accepted from the CDTRP Research Innovation competition per year.
- Grant funds should not be used as matching funding for a CDTRP training grant, and should not be used for clinical training.

REVIEW CRITERIA

All proposals will be first reviewed by the NIC to ensure eligibility and relevance to the terms of the competition. If a member of the NIC is involved in the grant application, or is deemed in conflict, he or she will recuse themselves from the decision making process.

Applications that are deemed to be either not eligible or not relevant to the competition will be removed from the competition and will not be evaluated by the Peer Review committee. All proposals will also be shared and reviewed for relevance purposes only by our funding partners to ensure that the application aligns to the individual partner requirements listed above.

A peer review committee will evaluate all relevant research proposals 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
- Suitable proposed timelines

Integration

- How would the proposal be integrated with the CDTRP and how does it fit with the specified CDTRP Theme?
- How would the project contribute to achieving the One-Transplant-for-Life vision of the CDTRP?

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 addition to the 3-page proposal, the application must:

- Submit a half-page summary of the research proposal that highlights how the research proposal help achieve the One-Transplant-for-Life vision to fulfill every donation opportunity and turn transplantation into a cure. This summary will be shared with partners and the NIC to assess the relevance of the application to the scope of the competition. (max ½ page);
- Attach a separate description of how the proposal will integrate and fit within a specific Theme of the CDTRP (max ½ page). **We encourage you to contact the lead of that Theme to get advice and suggestions on how to best integrate your project (www.cntrp.ca/nce-leads) - a support letter from the Lead is not required;**
- Attach a lay abstract (max. 250 words) that can be used to explain the proposal to the general public and that if funded could be posted publicly;
- Include a copy of a CIHR Academic Common CV for the Principal Applicant.
- Provide the names of 3 CDTRP Investigators that you suggest as potential reviewers for your application (www.cntrp.ca/investigators-and-associate-members). We will consider these names as either potential external reviewers or members of our peer review committee; however, we cannot guarantee that these individuals will be selected.

- Provide the names of individuals that you think would be in conflict and should NOT review your application.
- 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 PST on February 19, 2020**. 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 or unsigned applications will not be considered. Applicants must submit their application electronically to the CDTRP office as a single PDF file.

Suggested headings for the research proposal 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) Analysis of Data, 7) Anticipated Timeline, 8) Impact, Future research plans and Knowledge Translation, and 9) 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 CDTRP 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 as this funding cannot be used to support institutional overhead costs.

Research Grant Administration

A copy of the Research Grant Acceptance Form, signed by the Grant recipient, as well as receipt of evidence of ethics committee approval must be returned to the CDTRP prior to disbursement of Grant funds.

Studies must be designed to be completed within 18-24 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.

Patient Registration

The Grant recipient must agree to enroll recruited human subjects into the CDTRP patient registration database.

Progress Reports

The Grant recipient must provide a progress report to the CDTRP within 18-24 months of receipt of the Grant summarizing work completed, including presentations, abstracts and publications, as well as an accounting for funds. All progress reports will be shared with relevant funding partner(s).

Publications and Presentations

Grant recipients are expected to present their findings at scientific meetings, including the CDTRP 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 relevant funding partners forthwith.

Grant recipients are expected to list the CDTRP as one of their author affiliations in their related publications.

- All publications that result from a project supported by a ***CDTRP Research Innovation Grant*** should carry the following acknowledgement: “This research was supported by a *CDTRP Research Innovation Grant* funded by the Canadian Donation and Transplant Research Program.”
- All publications that result from a project supported by a ***CDTRP KFOC Research Innovation Grant*** should carry the following acknowledgement: “This research was supported by a *CDTRP KFOC Research Innovation Grant* jointly supported by the Kidney Foundation of Canada and the Canadian Donation and Transplant Research Program.”
- All publications that result from a project supported by the ***CDTRP CF Canada Research Innovation Grant*** should carry the following acknowledgement: “This research was supported by the *CDTRP CF Canada Research Innovation Grant* jointly supported by Cystic Fibrosis Canada and the Canadian Donation and Transplant Research Program.”
- All publications that result from a project supported by the ***CDTRP Addison Fund Research Innovation Grant*** should carry the following acknowledgement: “This research was supported by the *CDTRP Addison Fund Research Innovation Grant* jointly supported by the Addison Fund, the Transplant Research Foundation of British Columbia and the Canadian Donation and Transplant Research Program.”
- All publications that result from a project supported by the ***CDTRP UHN Research Innovation Grant*** should carry the following acknowledgement: “This research was supported by the *CDTRP UHN Research Innovation Grant* jointly supported by the University Hospital Network Multi-Organ Transplant Program and the Canadian Donation and Transplant Research Program.”
- All publications that result from a project supported by a ***CDTRP CLF Research Innovation Grant*** should carry the following acknowledgement: “This research was

supported by a *CDTRP CLF Research Innovation Grant* jointly supported by the Canadian Liver Foundation and the Canadian Donation and Transplant Research Program”

- All publications that result from a project supported by a ***CDTRP Paladin Research Innovation Grant*** should carry the following acknowledgement: “This research was supported by a *CDTRP Paladin Research Innovation Grant* jointly supported by Paladin Labs Inc. and the Canadian Donation and Transplant Research Program.”
- All publications that result from a project supported by the ***CDTRP UdeM Research Innovation Grant*** should carry the following acknowledgement: “This research was supported by the *CDTRP UdeM Research Innovation Grant* jointly supported by the Université de Montréal and the Canadian Donation and Transplant Research Program.”
- All publications that result from a project supported by the ***CDTRP SickKids Transplant & Regenerative Medicine Centre Research Innovation Grant*** should carry the following acknowledgement: “This research was supported by the *CDTRP SickKids Transplant & Regenerative Medicine Centre Research Innovation Grant* jointly supported by the SickKids Transplant & Regeneration Medicine Centre and the Canadian Donation and Transplant Research Program.”

Grant Recipient Responsibilities

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

- Study contract review and execution (for clinical studies)
- Must become a CDTRP Investigator (if not already one) and comply with all current CDTRP 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>, if applicable
- 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 and the CDTRP Evaluations Committee
- Integration of the study into the CDTRP 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 CDTRP Research Innovation Grant Competition

Grant recipients will be notified of the decision regarding funding in May 2020. Both successful and unsuccessful applicants will receive a summary and a constructive critique from the NIC.

Address for Submissions

Please send completed submissions, as a single PDF file, no later than **February 19, 2020 at 11:59pm PST** to:

Julie Turgeon
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