The Canadian **DONATION** and **TRANSPLANTATION** Research Program
Programme de recherche en **DON** et **TRANSPLANTATION** du Canada

# CDTRP Research Innovation Grant Competition – 2023
# Terms of Reference

## BACKGROUND

Since 2013, 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 2023 competition, the CDTRP will offer one (1) grant at $30,000 CAD. In addition, the CDTRP is proud to partner with the following organizations to provide further funding to support up to twelve (12) grants overall:

- **Transplant Research Foundation of British Columbia** (TRFBC):
  - The Venture Grants [2]
- **Kidney Foundation of Canada** (KFOC) [2]
- **Big Gifts for Little Lives** [1]
- **Alberta Transplant Institute/Paladin Labs Inc**. (ATI/Paladin) [2]
- **University Health Network Multi-Organ Transplant Program** (UHN-MOT) [1]
- **London Health Sciences Center** (LHSC) [1]
- **Université de Montréal** (UdeM) [1]
- **SickKids Transplant & Regenerative Medicine Centre** (SickKids) [1]

The CDTRP 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:** January 18, 2023
**Application Deadline:** April 12, 2023
**Notification Date:** Mid-June 2023
**Funding Start Date:** July 2023 (upon confirmation of REB approval)
**Study update submitted to NIC:** Within 18 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 five CDTRP Themes are:

1. Improve 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 $360,000, enough to support 12 grants of $30,000 CAD each (pending availability of partner funding).

Of the $360,000, we will support grants in the following strategic areas:

- **1 grant of $30,000 CAD** to support new research that addresses the *One-Transplant-for-Life* vision and aligns with one of the 5 Themes. This will be provided through the *CDTRP Research Innovation Grant competition* over an 18-month performance period with funding provided by the **Canadian Donation and Transplantation Research Program**.

- **2 grants of $30,000 CAD each** to support new and innovative research primarily focused on ***adult and/or pediatric solid organ transplantation and donation*** that addresses the *One-Transplant-for-Life* vision and aligns with one of the 5 Themes. Projects must include a patient, family, donor (PFD) engagement component in their design. Projects with a secondary focus on hematopoietic cell transplant must clearly outline how the intended research relates to solid organ donation or transplant research in order to be considered for this award. The Principal Applicant must hold the rank of assistant professor or higher and be based in **British Columbia.** The study can involve additional co-researchers, other sites and patients from across the country, provided the majority of research is conducted in **British Columbia.** The *Transplant Research Foundation of BC/CDTRP Venture Grants* will be funded by the **Transplant Research Foundation of British Columbia** over an 18-month performance period.

- **2 grants of $30,000 CAD 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 projects can fall under any of the four research pillars of the KFOC (biomedical, clinical, health systems, & population health). The Kidney Foundation of Canada encourages research projects which include lived-experience expertise on the application team, although this is not mandatory. KFOC will require Foundation specific

financial and scientific reporting, for any questions, please reach out to Christine.marquis@kidney.ca. Please note that KFOC will only approve one, 6 month no cost grant extension under exceptional circumstances. The *CDTRP KFOC Research Innovation Grants* will be funded by the **Kidney Foundation of Canada** over an 18-month performance period.

- **1 grant of $30,000 CAD** to support new research related to pediatric transplantation that addresses the One-Transplant-for-Life vision and aligns with one of the 5 Themes. The project must be based in Edmonton, Alberta and must also be focused on pediatric heart transplantation. This will be provided through the CDTRP Big Gifts for Little Lives Research Innovation Grant competition respectively over an 18-month performance period

- The Alberta Transplant Institute (ATI) in partnership with Paladin Labs Inc. will provide **two (2) additional grants of $30,000 CAD each** to the top ranked **unfunded Alberta-based researchers** through the *CDTRP ATI/Paladin Research Innovation Grant* competition over an 18-month performance period.

- The UHN-MOT will provide **1 additional grants of $30,000 CAD each** to the top ranked **unfunded UHN researchers** through the *CDTRP UHN Research Innovation Grant* competition over an 18-month performance period.

- The London Health Sciences Center will provide **1 additional grant of $30,000 CAD** to the top ranked **unfunded LHSC researcher** through the *CDTRP LHSC Research Innovation Grant* competition over an 18-month performance period.

- The Université de Montréal will provide **1 additional grant of $30,000 CAD** to the top ranked **unfunded UdeM researcher** through the *CDTRP UdeM Research Innovation Grant* competition over an 18-month performance period.

- The SickKids Transplant & Regenerative Medicine Centre will provide **1 additional grant of $30,000 CAD** to the top ranked **unfunded SickKids researcher** through the *CDTRP SickKids Research Innovation Grant* competition over an 18-month performance period.

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

**ELIGIBILITY AND RELEVANCE**

The CDTRP shall receive and process applications and evaluate the submitted proposals for relevance and eligibility to the competition before peer review. Proposals will be deemed eligible and relevant based on the following:

**Eligible Applicants**

The Principal 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 CDTRP structure if funded and agree to become a participating CDTRP Investigator.
- All stages of research career are eligible for funding, but CDTRP wants to give priority to Early Career Researchers (in the first five years of their academic appointment).
- Postdoctoral research trainees are invited to apply with their supervisor or director as co-principal applicants.
- 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 an author affiliation.
- 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.
- Investigators who receive CDTRP ATI/Paladin Research Innovation Grants are expected to become members of the ATI if they are not members at the time of application.

**Eligible Research Proposals**

In 2023, 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. All Innovation Grant applicants are required to outline how their research addresses a patient priority. Applicants must outline the significance, feasibility, and integration of PFD in their project.

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 18 months of receipt of funding; no renewals will be considered and extensions beyond 18 months will be considered under exceptional circumstances only.

**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 CAD 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 2022 CDTRP 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 Grant competition per year.
- Investigators who have final project reports outstanding from any TRFBC competition at the application deadline will not be eligible to receive the TRFBC funded grants.
- Investigators who have final project reports outstanding from any KFOC competition at the application deadline will not be eligible to receive the KFOC funded grants.
- Grant funds may not be used for clinical training.

**REVIEW CRITERIA**

All proposals will be first reviewed by the CDTRP to ensure eligibility and relevance to the terms of the competition. 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. If a member of the CDTRP Peer Review committee is involved in the grant application, or is deemed in conflict, he or she will recuse themselves from the decision-making process. 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, which will include patient, family and donor (PFD) partners, will evaluate all relevant research proposals based on the following criteria:

| Criteria | Scientific Reviewer Description | PFD Reviewer Description | Points* |
|---|---|---|---|
| Significance | The study contributes to advancing scientific knowledge with clinical relevance and applicability. | The study contributes to advancing scientific knowledge that is significant to patient, family, or donor priorities. | /5 |
| Feasibility | The study design is clearly stated and appropriate for the research question; methods are appropriate and rigorous with an appropriate budget and timeline. | For studies with human participants, the study has proposed a feasible participant recruitment strategy that considers how involvement may impact participants and has an appropriate budget and timeline. | /5 |

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|---|---|---|---|
| | | For studies without human participants, the study has clearly demonstrated translational potential in humans. | |
| PFD Engagement | PFDs are engaged as partners, as appropriate for the study. The applicant has outlined how PFD engagement has strengthened the project.<br><br>The proposed roles and responsibilities for PFD partners across the research cycle are clearly described if the engagement has yet to happen.<br><br>If the applicant determines PFD engagement is not applicable, it is well justified. | PFDs are engaged as partners, as appropriate for the study. The applicant has outlined how PFD engagement has strengthened the project.<br><br>The proposed roles and responsibilities for PFD partners across the research cycle are clearly described if the engagement has yet to happen.<br><br>If the applicant determines PFD engagement is not applicable, it is well justified | /5 |
| CDTRP Integration | The study relates to CDTRP's research themes and/or cross-cutting priorities and outlines how the project will be integrated within CDTRP, and how knowledge will be disseminated. The project supports CDTRP's vision of 'One Transplant for Life'. | The study relates to CDTRP's research themes and/or cross-cutting priorities and outlines how the project will be integrated within CDTRP, and how knowledge will be disseminated. The project supports CDTRP's vision of 'One Transplant for Life'. | /5 |
| | **TOTAL** | | **/20** |

***Points rating scale:** 5 = excellent; 4 = very good; 3 = satisfactory; 2 = fair; 1 = poor

**GUIDELINES FOR APPLICATION SUBMISSION**

Research Proposal and Figures/Tables:

- 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.
- Suggested headings 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, and 8) Impact, Future research plans and Knowledge Translation.

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

a) The contact information requested in the application form, including the optional EDI questions. This page will be removed from your application prior to review.
b) The names of individuals that should NOT review your application, with justification.
c) A half-page **summary of the research proposal** that highlights how the research proposal helps achieve the *One-Transplant-for-Life* vision to fulfill every donation opportunity and turn transplantation into a cure. This summary will be used by the NIC and shared with funding partners to assess the relevance of the application to the scope of the competition. (max ½ page)
d) A **lay abstract** (max 250 words) that can be used to explain the proposal to PFD reviewers and the general public and that could be posted publicly if funded. This abstract should be free of jargon, technical or undefined scientific terms, and written in a manner that is easily understood by someone without prior knowledge of the subject. To help you with the lay abstract, you can use these tools: https://hemingwayapp.com/; https://healthresearchbc.ca/bc-support-unit/info-and-resources/information-for-researchers/plain-language-guide/
e) **References** (no page limit)
f) A one page description of the **budget and justification**.
g) A separate description of **how the proposal will integrate within a specific Theme** of the CDTRP (max ½ page). *We encourage you to contact the Lead or Manager of that Theme to get advice and suggestions on how to best integrate your project (https://cdtrp.ca/en/research/) - a support letter from the Lead is not required.*
h) An explanation of how **sex**, as a biological variable, **gender**, as a socio-cultural factor, and **diversity** are taken into account in the research design, methods, analysis and interpretation, and/or dissemination of findings, or explain why they are not relevant / feasible within the scope of the project. For guidance and resources on how to integrate sex and gender into research, please consult the CIHR website: https://cihr-irsc.gc.ca/e/50836.html (max ½ page).
i) Engaging patients, families, and donors in CDTRP support research is a core value for our Network. As outlined in CDTRP's PFD Terms of Reference, patient engagement requires meaningful and active collaboration between researchers and PFDs in governance, priority setting, conducting research, and knowledge translation.
Engaging PFD partners, especially at the beginning of the project, will help direct research that focuses on patient priorities and improves patient outcomes. Note, CDTRP

recognizes that the level of engagement will be different depending on the scope of your project and scientific design.

All Innovation Grant applicants are required to outline **how their research addresses a patient priority and outline the significance, feasibility, and integration of PFD in their project**.

All applications must answer the below questions (max 1 page).

- Describe how this project supports patient, family, or donor priorities
- Describe how your research question and design consider the potential impact of PFD involvement.
- Describe how you've actively engaged with PFD partners, thus far. If you have not engaged yet, describe the key roles and responsibilities you envision for PFD partners. If not applicable, state why.
- Describe how your project has been strengthened with PFD involvement. If you have not engaged yet, describe how your project will benefit from PFD engagement. If not applicable, state why.

CDTRP's PFD Partnership Platform Manager Manuel Escoto (mescoto@cdtrp.ca) would be pleased to provide support and feedback as you are developing your application.

In addition, you may reference the resources below when developing your plan.

- CIHR Patient Engagement Training
- Saskatchewan Centre for Patient-Oriented Research
- Alberta SPOR Support Unit
- Michael Smith Health Research BC Resource Library
- Newfoundland and Labrador Support Unit
- BC Patient Safety & Quality Council, A Guide to Patient Engagement
- Can-SOLVE CKD Network Training Modules
- Evidence-Informed Practices and Strategies for Patient-Oriented Research (POR): A 'Menu' for Research Teams

Note: PFD remuneration ($50/hr) is an eligible grant expense. For more information on the CDTRP PFD platform, please visit our website: CDTRP PFD Partnership platform. **All applications for TRFBC grants must include a PFD Engagement Plan.**

j) A copy of a CIHR BioSketch Common CV for the Principal Applicant.

k) Optional: 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 submitted electronically (by using the link) no later than **11:59pm PST on April 12, 2023**. 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 using this link: https://survey.ca1.qualtrics.com/jfe/form/SV_cOSSWV6Xq5QblaK

The applicant must use Calibri or Arial font, size 12 points or larger. Use at least 2 cm (3/4 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 / Animal Care Committee approval**

The successful applicant must provide evidence of appropriate Research Ethics Board / Animal Care 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 Research Ethics Board / Animal Care Committee approval must be returned to the CDTRP prior to disbursement of grant funds.

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 CDTRP within 18 months of receipt of the grant summarizing work completed, including presentations, abstracts and publications, and 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 affiliate Theme meeting (within the first 6 months and at the end of the project), and to submit their work for publication in peer-reviewed journals. The CDTRP shall require a copy of all proposed publications upon submission for publication or other public disclosure and the CDTRP shall provide said information to relevant funding partners.

Grant recipients are expected to list the CDTRP as an author affiliation 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 Transplantation Research Program."

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- All publications that result from a project supported by the ***Transplant Research Foundation of BC/CDTRP Venture Grant*** should carry the following acknowledgement: "This research was supported by the *Transplant Research Foundation of BC/CDTRP Venture Grant,* jointly supported by the Transplant Research Foundation of British Columbia and the Canadian Donation and Transplantation 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 Transplantation Research Program."

- All publications that result from a project supported by the ***CDTRP Big Gifts for Little Lives Research Innovation Grant*** should carry the following acknowledgement: "This research was supported by the *CDTRP Big Gifts for Little Lives Research Innovation Grant* jointly supported by the Big Gifts for Little Lives campaign and the Canadian Donation and Transplantation Research Program."

- All publications that result from a project supported by the ***CDTRP ATI/Paladin Research Innovation Grant*** should carry the following acknowledgement: "This research was supported by the *CDTRP ATI/Paladin Research Innovation Grant* jointly supported by the Alberta Transplant Institute, Paladins Lab Inc. and the Canadian Donation and Transplantation 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 Transplantation Research Program."

- All publications that result from a project supported by the ***CDTRP LHSC Research Innovation Grant*** should carry the following acknowledgement: "This research was supported by the *CDTRP LHSC Research Innovation Grant* jointly supported by the London Health Sciences Center and the Canadian Donation and Transplantation 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 Transplantation Research Program."

- All publications that result from a project supported by the ***CDTRP SickKids Research Innovation Grant*** should carry the following acknowledgement: "This research was supported by the *CDTRP SickKids Research Innovation Grant* jointly supported by the SickKids Transplant & Regenerative Medicine Centre and the Canadian Donation and Transplantation 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
- Integration of the study into the CDTRP structure
- Provide requested materials for award announcement (picture and short biography). Recipients will be expected to comply with requests made by the funder to provide additional project details.
- Provide a final written progress report to the CDTRP, including an explanation of any left-over funds, which will be shared with the funding partner if applicable.
- Forward copy of abstract(s)/manuscripts(s) to the CDTRP 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.

**ADDRESS FOR SUBMISSIONS**

Please send completed submissions, no later than **April 12, 2023 at 11:59pm PST** using this link: https://survey.ca1.qualtrics.com/jfe/form/SV_cOSSWV6Xq5QblaK

**Notification of Decision for the CDTRP Research Innovation Grant Competition**

Grant recipients will be notified of the decision regarding funding mid June 2023. Both successful and unsuccessful applicants will receive a summary and a constructive critique from the CDTRP Peer Review committee.