

Program Details Rapid Response 2024

Background

For three generations, the Weston Family Foundation has pursued its mission to enhance and enrich the lives of Canadians. With a focus on health and landscapes, the Foundation aims to catalyze inquiry and innovation to bring about long-term change. Now in its sixth decade, the Foundation continues to collaborate with a broad range of Canadian charities to further world-class research, explore new ideas, and create tangible benefits for the communities in which it works.

Today, the Foundation takes a leadership role in tackling large problems, in both health and landscapes, thar are under-addressed. Among these, neurodegenerative diseases (NDAs) such as Alzheimer's and Parkinson's disease, are placing a particularly large and increasing physical, emotional, and financial toll on the individuals they affect, their families and the society at large. Therefore, the Foundation, through its Weston Brain Institute (the "Institute), seeks to accelerate the development of therapeutics and tools that address the unmet need for effective ways to prevent, diagnose and/or treat NDAs.

The Rapid Response program was designed to address this challenge by providing seed funding to quickly identify and validate novel, high-risk, high-reward ideas that have the potential to be translated into impactful therapies for NDAs. Through this and other programs, the Foundation aims to catalyze and scale science-based approaches to significantly improve the health and well-being of Canadians.

Important things to know about the Foundation:

- Focus is on translational research.
- **Funds are provided contingent on meeting milestones.** If your project is awarded, funds are provided in tranches when milestones are successfully completed.
- Our application process is interactive. We strongly encourage all potential applicants to reach out should there be any questions about the program (e.g., if you wish to discuss the eligibility or fit of your project). During the review process, you may receive additional questions from the review committee that need to be addressed prior to final decisions being made to invite a project to submit a full Proposal or for a project to be recommended for funding.
- Many projects are declined at the Letter of Intent (LOI) stage. Historically, only
 ~15% of LOIs are invited to the Proposal phase, so that applicants and reviewers spend their
 time on Proposals that have an excellent chance of being funded.
- Proposal funding rates have ranged from 30-50%.
- We provide more than funding. Our grantees may also benefit from opportunities such as, the

expert advice from our scientific advisors, industry exposure, networking, and international collaboration opportunities.

Section 1 Scope and Other Project Considerations

The Rapid Response 2024 program seeks to support translational research that can accelerate therapeutic or tool development for neurodegenerative diseases of aging (NDAs), as defined by the Institute (see the "Institute definitions" section found at the end of this document). Basic/discovery research, including but not limited to understanding disease mechanisms, discovering genes implicated in disease, and identifying new therapeutics targets, is not in scope.

Therapeutics should address unmet needs in the prevention, treatment and/or symptomatic management of NDAs. Tools should address challenges in translational research to accelerate the development and/or clinical implementation of therapeutics for NDAs (e.g., biomarkers, drug delivery systems). Projects covering only the discovery/identification of a tool are considered out of scope.

Preliminary data are required for this program, which should serve to support the rationale, hypothesis, and feasibility of the study.

Section 2 Funding Specifications

Total funding: The Foundation is able to fund many grants through this program. Grants are contingent on the receipt of high-quality applications.

Funds available per project:

- Up to \$300,000 per project over up to 18 24 months, as determined by the Foundation. Funding requested should clearly reflect the amount needed to complete the aims of the study.
- Funds will be granted only for direct costs that are appropriate and justifiable for the work proposed.
- Funds cannot be used for large equipment purchases unless prior written approval from the Foundation has been obtained.
- Funds cannot be used for administrative or indirect costs or for salaries for people who already receive salaries from their institutions.
- Travel expenses to scientific conferences/meetings to present work and publication costs associated with the awarded projected can be included in the budget.
- Each significant item and its cost must be clearly described in the budget (at the Proposal stage only).
- The amount granted may not be for the full amount requested if the review committee only recommends part of the grant for funding.
- A proportion of the funds can be used for unique international resources (e.g., in-licensing IP, costs associated with accessing a database). However, it is expected that the majority of the funds will go towards work conducted in Canada.

Any grant provided by the Foundation pursuant to this Program shall be directed to the qualified grantee

institution and not to any individual. Responsibility for the planning, direction, and execution of the proposed project will rest solely with the Applicants.

Multiple institutions: In the event of collaboration between multiple institutions, it is the responsibility of the Principal Applicant to distribute/manage funds appropriately.

Full or partial support of projects: The Foundation may provide full or partial funding support for a given application. If there is interest in supporting only a portion of a project, applicants will be asked to revise the application to reflect the portion of interest.

Larger projects: The Foundation may support an application that is part of a larger project. While the application may describe how the proposed work fits into the larger project, the primary focus of the application should be on details of the proposed work. Similarly, the application should ensure that funding requested from the Foundation for the proposed work does not overlap with funding from other sources that are supporting the larger project. In the review of such applications, the criteria for granting will only be applied to the part of the project that is requesting funding from the Foundation.

Conditional funding and milestones: Tranche payments are conditional on grantees meeting predetermined milestones and providing deliverables, including submission of progress reports, financial reports and participation in Foundation sponsored Research Days. Funding is not automatic and is contingent upon the grant progress being favorably reviewed by the Foundation.

Supplemental funding: The Foundation encourages grantees to seek additional funds to further their work. The Foundation has no guaranteed policy for renewal or continuation of grants. The Foundation may, at its discretion, seek to further support clearly successful projects. Grantees are also eligible to apply for funding through other Foundation programs.

Section 3 Application Process

The application process consists of two stages: Letters of Intent (LOIs) and Proposals. To apply, applicants must submit an LOI to the Foundation. Selected applicants will then be invited to submit a Proposal. Both the LOI and Proposal must be completed and submitted through the Foundation's online grants management system (<u>https://westonfdn.smartsimple.ca/</u>). Each LOI and Proposal is peer-reviewed by a scientific review committee.

The LOI stage of the application process is a significant stage of evaluation. LOIs that meet the rigorous review criteria will be invited to submit a Proposal. Historically, only a small proportion of LOIs (~15%) are invited to the Proposal stage, and approximately 30-50% of Proposals are recommended for funding. This process ensures that LOIs are easy to submit so that good ideas are not missed, while ensuring that applicants taking the time to write full Proposals have a very good chance of being funded. Budgets are only required at the Proposal phase.

If awarded, applicants must ensure that the grant agreement is reviewed and signed within 4 weeks of notification of selection; otherwise, the Foundation reserves the right to cancel the grant.

Section 4 Review Criteria

The review committee will consider the criteria listed below when reviewing LOIs. In addition, applicants will be evaluated on whether their project has been designed to align with the proposed path to impact (i.e., knowledge mobilization plan).

*Knowledge mobilization: The Weston Family Foundation is committed to delivering measurable impacts to the well-being of Canadians. With this aim, it is important to the Foundation that all funded projects intentionally undertake efforts to mobilize the knowledge generated by the project to those who can act upon it or ultimately benefit from it. These efforts should engage interested and relevant parties and help make the project's knowledge meaningful for policy, product or practice.

- Impact:
 - If successful, will the project advance the development of therapeutics for NDAs towards clinical impact across diverse populations in Canada?
 - Does the project address an important problem, unmet need or critical barrier to progress in the field? What populations or sub-populations in Canada may benefit from the study?
- Experimental approach:
 - Is the overall strategy, methodology and analyses well-reasoned and feasible, supported by strong preliminary data, and appropriate to accomplish the specific aims of the project? Are potential problem areas and common pitfalls adequately considered and addressed? Is the project reasonably powered? If applicable, does the recruitment plan include efforts to recruit from a diverse population?
- Innovation:
 - How is the therapeutic or tool different from other approaches that are in development?
 - Does the project challenge and/or advance current paradigms and theories?
 - Will the work refine, improve or be a new application of theoretical concepts, approaches, methodologies, instrumentation, or intervention?
 - If successful, is the project likely to attract venture or pharma interest to further develop/commercialize the therapeutic/tool?
- Fit: Is the project, including its scale and scope, appropriate for this program?

Additional criteria considered when reviewing Proposals:

- Risk appropriateness:
 - Is the scientific risk (likelihood that the hypothesis will not be supported) commensurate with the potential reward of the project if successful?
 - Has executional risk (the likelihood that the project cannot be completed as outlined) been addressed as much as is reasonable?
- Knowledge mobilization (KM):
 - Is the proposed KM plan well-thought out and potentially able to achieve meaningful impact?
 - Does the current project align well with the proposed KM plan?
 - Are the co-production partners, milestones and timelines listed in the KM plan appropriate for the achievement of the plan? For example,

- Are there clear and appropriate next steps after this study to continue development if successful?
- Has the applicant considered the scientific and regulatory requirements that are necessary to move the project to the next stage of development, out-licensing and/or company formation?
- Has the applicant and/or institution developed intellectual property protection for the therapeutic approach? If not, is there a clear strategy and timeline to do so?

• Team and environment:

- Are the investigator and investigative team appropriately trained and well-suited to carry out this work?
- Does the team have experience with projects of similar scope and complexity?
- If needed, does the investigative team have the infrastructure support and/or a track record of success to further develop the therapeutic approach (e.g., out-license, company formation)?
- Does the scientific environment in which the work will be conducted contribute to the probability of success? Does the proposed work take advantage of the unique features of the scientific environment or employ useful collaborative arrangements?

• Milestones and Timeline:

- Are the milestones and timeline realistic yet aggressive for the proposed project?
- Are there clear and appropriate go/no-go criteria, quantifiable outcome measures, and clear endpoints for each tranche of funding?
- Budget:
 - Is the budget appropriate for the research proposed?
- Other as needed.

Section 5 Eligibility of Applicants

For this program, the Institute is only able to accept LOIs and Proposals from institutions (or individuals affiliated with and applying through or on behalf of institutions) that are Canada Revenue Agency (CRA) qualified donees located in Canada. Applicants may appear in any role on any number of applications.

- Eligible Principal Applicants must be a researcher working in Canada at least 50% of the time and hold a position at or above the level of Assistant Professor or equivalent at a CRA qualified donee institution located in Canada.
- Co-applicants must be at the post-doctoral level or above and working at a CRA qualified donee institution located in Canada.
- Collaborators must be at the post-doctoral level or above and can be working outside of Canada.

For definitions of Principal Applicants, co-applicants, and collaborators, please refer to the "Institute definitions" section at the end of this document.

The Foundation highly encourages collaboration within the research community and across multiple disciplines. Applicants should consider collaborations where possible to maximize the impact of their project.

Proposals submitted to this Program must be approved by the institution on whose behalf or through which the Proposal is being submitted. However, LOIs do not need to be approved in this manner.

Section 6 Expected Project Outcomes

The Foundation assesses the impact of awarded grants through the results and outcomes achieved for each project. It is important that projects aim to achieve outcomes that can address the goals of the Rapid Response 2024 program and the overall mission of the Foundation.

Outcome	Measure (e.g.,)
Commercial Developments	IP filings/disclosure, license agreements
Leveraged Funding	Additional funding support
Non-Peer Reviewed Content	Mentions/coverage via traditional news outlets, conference/meeting presentations
Peer-Reviewed Content	Scholarly publications (e.g., journal articles)
Partnerships/Collaborations	New partnerships/collaborations (academic, industrial)
Resources	New research tools (e.g., cell/animal models, assays, libraries), new methodology, datasets

The following are examples of outcomes that may be expected.

Section 7 Reports and Assessments

Principal applicants must complete the following if a grant is awarded. Templates for reports will be provided by the Institute:

Reports:

- A milestone and a financial update are due approximately every 6 months, and prior to each scheduled tranche payment. This serves to provide an update on the completion of project milestones mutually agreed upon by the grantee and the Foundation.
- A progress report is due annually and includes a milestone report, a budget report, relevant data, and an update on outcomes (e.g., publications, conference presentations, additional funding). A telephone discussion with the grantee, may be requested by the Foundation.
- At the mid-point of each tranche (i.e., 3 months before the end of a 6-month tranche), the grantee will be reminded about the report due date and must confirm that the project is on track. If the grantee is facing any challenges, they are asked to notify their assigned program manager immediately.

• If applicable, grantees will submit participant recruitment reports at least every 3 months to ensure that recruitment is on track.

The grant is paid in tranches tied to the 1) successful completion of milestones and 2) achievement of the 'go' criteria at 'go/no-go' decision points.

Post-award Follow-up:

• Institute staff will follow-up with the grantee at 1, 3, and 5 years after project completion to capture outcomes related to the funded project. This information will be used to assess the project's readiness for additional funding support from the Foundation (e.g., through Follow-on Funding) and/or assist with finding collaborators, funders or other partners to move the innovation to the next stage of development.

Mentorship: Depending on the scope of the project, a grantee may be paired with 1-2 experts to discuss progress, challenges with the project and receive advice on next steps in the development path. Mentors will meet grantees following the submission of a milestone/progress report.

Research Day: The grantee or a team member on the grant must attend one Research Day per year to report on the progress of the project, unless otherwise notified by the Foundation. Additional key personnel may also attend if approved by the Foundation.

Foundation member site visits: Foundation members (i.e., Institute staff or Foundation Board members) may wish to visit grantees to see project work underway. These visits are not mandatory, and consent of grantees will be requested prior to the visit. The Foundation hopes that grantees will welcome this opportunity.

Financial accountability: Grantees are expected to account for the moneys expended under any Foundation grant; any moneys spent either not in accordance with the approved research project or prior to pre-approval of any material change in the project are both recoverable and subject to restitution by the grantees to the Foundation and may be cause for immediate termination of funding. Any funding provided beyond what is needed for the agreed upon research must be immediately reported to the Foundation. The Foundation will then advise how the funding may be directed.

Section 8 Confidentiality

The Foundation treats all LOIs, Proposals, research projects and associated research information (collectively, the "Confidential Information") in confidence using reasonable care in protecting such Confidential Information from disclosure to third parties who do not participate in the grant review process and Foundation assessments. All Confidential Information will be used by the Foundation and its scientific review committee for the purposes of reviews and assessments and will be shared only in accordance with the sharing policy as set out herein. Notwithstanding the foregoing, Confidential Information shall not include any information that:

- a) was generally known to the public prior to the effective date of this Program announcement;
- b) becomes generally known to the public through no unlawful or unauthorized act by any

recipient of Confidential Information; or

c) was independently developed by the Foundation or its scientific review committee without reference to the Confidential Information.

If the Foundation or any of its scientific review committee members are requested to disclose Confidential Information pursuant to a legal or governmental proceeding, the Foundation shall give the Applicant or other owner(s) of such Confidential Information notice of such disclosure request as soon as is reasonably practicable.

Section 9 General Information

Institutions and individuals affiliated with and applying through or on behalf of institutions (collectively, "Applicants") should carefully discuss the Program announcement and the terms of this document with the appropriate office at their institution before submitting an application. The submission of an LOI or a Proposal does not bind either the Foundation or the Applicants by any commitment to provide or receive funding, respectively. Successful Applicants will be required to agree to terms substantially similar to those contained in this document and the Foundation reserves the right to alter, delete or add additional terms in the grant agreement between the successful Applicants and the Foundation.

The Foundation reserves the right to accept or reject any or all applications at its discretion and to negotiate the terms of the specific grant agreement with Applicants.

The Foundation, at its sole discretion, may change the timeline of the application process.

Section 10 Other

Liability and Indemnity

Each Applicant pursuant to this Program acknowledges and agrees in responding to the Program announcement that the Applicant shall have no claim against the Foundation, and its respective representatives, related companies or affiliates, should such Program response be unsuccessful for any reason. Each Applicant hereby remises and releases the Foundation, its representatives and affiliates, from any cause of action, complaint, or claim in connection with the Research Funding Announcement (RFA) process and its outcome.

The Foundation's role in grants awarded pursuant to this Program is that of a funder. The Foundation is not the sponsor of funded projects. As such, the Foundation will not assume any liability associated with funded projects and each Applicant who is ultimately awarded a grant pursuant to this Program releases the Foundation from any and all liability with respect thereto and further indemnifies the Foundation, and its respective representatives and affiliates, from any claim or loss whatsoever associated with the applicable grant.

Intellectual Property Policy and Intellectual Property Agreements among Collaborators

The Foundation acknowledges that any intellectual property ("IP") that arises from research funded through this Program, including discoveries, is not the property of the Foundation.

The Foundation requires that researchers and collaborators agree on any material IP issues prior to submission of a Proposal.

Publication and Sharing Policy

The Foundation expects results of funded research to be published as rapidly as possible in open access scientific literature or other forms of publication that are readily available to the general public and/or research community. Such publication should be consistent with high standards of scientific excellence and rigor and provide sufficient detail so the research community can benefit from the findings from or in connection with the funded project.

A lay person abstract of the research proposal must be submitted prior to funding. A lay person abstract of the research results must also be submitted no later than 9 months from the date of grant expiration. These abstracts may be made available to the public by the Foundation.

Any presentation, releases, papers, interviews, publication or other forms of communication dealing with the awarded project or the results from the awarded project must acknowledge the funding provided by the Foundation, in a manner proportionate to the contribution of the Foundation. Any other use of the Foundation's intellectual property, including its name, logo or trademark requires prior written permission of the Foundation.

All tools or reagents (i) funded by and (ii) that result from funded projects should be made readily available to the research community either freely or at reasonable prices within 9 months of study completion. If sharing of such tools or reagents will jeopardize the Applicant's right to secure patents or copyrights necessary to protect the Applicant's ownership, then they should be made available as soon as these rights have been secured. The Foundation may let the public know of these tools or reagents so other researchers know they are available.

The Foundation encourages sharing of data and making raw data publicly available where possible.

The Foundation requires any clinical trial awarded under any of its funding programs be registered with clinicaltrials.gov, or other appropriate public registry.

Section 11 Institute definitions

Neurodegenerative diseases of aging: Alzheimer's disease, frontotemporal dementia, dementia with Lewy bodies, multiple system atrophy, Parkinson's disease, progressive supranuclear palsy, vascular contributions to the listed diseases, and prodromes to the listed diseases (e.g., mild cognitive impairment as prodromal to Alzheimer's disease; REM sleep behavior disorder as prodromal to Parkinson's disease).

Therapeutic: A pharmacological approach (including small molecules, biologics, cell therapies, and vaccines, including drug repositioning and repurposing), medical device, surgical intervention, or magnetic or electrical brain stimulation.

Clinical trial: Research in which one or more human subjects are prospectively assigned to one or

more interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Translational research: Applied research towards developing therapeutics for the prevention, treatment and/or symptomatic management of human disease. For example, for small molecule drug development, this includes target validation to phase II clinical trials. Basic/discovery research, including but not limited to understanding disease mechanisms and discovering genes implicated in disease, is not in scope.

Tool: An item that accelerates translational development of therapeutics, e.g., biomarkers, *in vivo* assays, drug delivery systems.

- Tools must have direct impact on the translational development of therapeutics for neurodegenerative diseases of aging and will be valued only on their ability to do this.
- Any value the tools contribute to basic research will not be taken into consideration. For example, tools will not be valued for their ability to identify new targets or understand disease mechanisms.
- Projects covering only the discovery/identification of a tool are out of scope.
 - For biomarkers:
 - Biomarkers must be under development for human disease diagnosis, prognosis, patient stratification to clinical trials, measuring disease progression, and/or to predict/measure response to therapy (e.g., surrogate for a clinical endpoint).
 - Biomarkers should measure pathology of the disease (e.g., fluid, imaging or tissue biopsy derived biomarkers) and not be based on cognitive, neuropsychological or behavioural phenotypes (e.g., gait or grip strength). Genetic biomarkers including somatic mutations, SNPs, epigenetics and gene products are in scope if they meet the other eligibility criteria.
 - For cognitive assessment tools,
 - If developing a cognitive assessment tool or clinical assessment instrument, the tool must be being tested in patients with a relevant disease.
 - Requires discussion of why the new assessment would be better than existing ones.

Principal Applicant:

- The individual who, with the other co-applicants, is responsible for overseeing the planning, direction, and execution of the proposed project. **Only one team member can be designated as the Principal Applicant.**
- The Principal Applicant is responsible for handling all correspondence with the Foundation. This includes submitting any requested information.
- If awarded the grant, the Principal Applicant is responsible for managing funds and ensuring that at least one applicant on the grant attends all assessment meetings.
- The Principal Applicant must hold a position at or above the level of Assistant Professor or equivalent and be working at least 50% of the time at a CRA qualified donee institution located in Canada. Funds will be paid to the institution that the Principal Applicant is affiliated with and appointed at.

Co-Applicant(s):

• Individual(s) who, with the Principal Applicant, are responsible for the planning, direction, and execution of the project.

• Co-Applicants must be at the post-doctoral level or above and working at a CRA-qualified donee institution located in Canada.

Collaborator(s):

- Individual(s) who contribute substantially to the project but do not lead the work.
- Collaborators must be at the post-doctoral level or above and can be working outside of Canada.

For any questions regarding the program please contact Dr. Teenu Sanjeevan at 647-265-1935, teenu.sanjeevan@westonfoundation.ca