Transformational Request for Proposals on

Neurodegenerative Diseases of Aging - Main Document

1. About The W. Garfield Weston Foundation

The W. Garfield Weston Foundation (the “Foundation”) is a private Canadian family foundation first established in the 1950’s by Willard Garfield Weston and his wife Reta, with their shares in the family company, George Weston Limited. Today this business also includes Loblaw Companies Limited.

The Founders believed that as the funds were generated through the hard work and success of Canadian businesses, the grants should be given in Canada for the benefit of Canadians.

Donations from the Foundation are directed to Canadian registered charities or other qualified donees in the fields of education, land conservation, and science in Canada’s North. Each year, the Foundation also allocates a number of unsolicited Trustee Initiated Grants which cover a broad range of interests.

1. Details of the Request for Proposals

The goal of this request for proposals (“RFP”) is to provide funding to high potential, translational research or clinical trials that will have transformational impact in neurodegenerative diseases of aging.

Appropriate projects are those that would be rated excellent to outstanding in a stringent peer review process.

To be eligible, projects must fall into one of these two categories to be considered:

* Preclinical to Phase III development of a therapeutic
* Development of tools that help accelerate the development of therapeutics e.g., animal models, imaging techniques or reagents, biomarkers or diagnostics

The Foundation defines translational and therapeutic as follows:

* **Translational**: Applied research towards developing therapeutics for the prevention and/or treatment of human disease (e.g., for small molecule drug development, target validation to early Phase II clinical trials).
* **Therapeutic**: Drugs (including small molecules, biologics, cell therapies and vaccines), medical devices or surgical interventions regulated by regulatory bodies such as the FDA. This definition includes therapeutics for all stages of disease including symptomatic relief, prevention, diagnosis and disease modification, but does not include complementary approaches such as exercise or acupuncture.

The basis for funding will be impact on neurodegenerative diseases of aging; however, research may be in any disease. Of diseases that affect more than 1,000 Canadians, the Foundation considers the following to be neurodegenerative diseases of aging:

* Alzheimer’s disease
* Parkinson’s disease
* Dementia with Lewy Bodies
* Frontotemporal dementia
* Amyotrophic lateral sclerosis
* Multiple system atrophy
* Mild cognitive impairment as prodromal to one of the above diseases

The Foundation will commit up to $4 million to this funding program. Grants can be up to $500,000 per project each year over three years to a maximum of $1.5 million per project. Grants can only be awarded to institutions that are registered charities in Canada.

1. Timeline

The Foundation employs an expedited granting mechanism with the hope of impacting patients quickly. These timelines are approximate and may be subject to change.

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| **Letter of Intent (LOI) Deadline** | Monday, March 25th, 2013 11:00AM EST |
| **Anticipated Proposal Invite** | Early May, 2013 |
| **Anticipated Proposal Deadline** | Mid-June, 2013 |
| **Anticipated Award Announcement** | July, 2013 |

1. Application Process

There are two stages to the application process: Letters of Intent (LOIs) and Proposals.

**Letters of Intent (LOIs)**

To submit an LOI, send the completed template at the end of this document by email to info@westonneuroscience.ca by 11:00AM EST, Monday March 25th, 2013. The template contains instructions to help you complete it. A complete Letter of Intent consists of a cover page, applicant details and answers to the letter of intent questions. LOIs must be in English and in a word processing program (e.g., Microsoft Word).

Applicants may appear in any roles on any number of LOIs. One LOI per proposed project is required.

**Review Process**

Each LOI will be peer reviewed by a scientific review committee. Applicants whose LOIs meet the RFP review criteria and are favourably reviewed will be invited to submit a Proposal. These applicants will receive the Proposal instructions and templates with their invitation. Complete Proposals will be peer reviewed by the scientific review committee, and feedback will be provided to applicants who do not receive grants.

1. Review Criteria

**Criteria considered when reviewing LOIs and Proposals:**

* **Innovation**: Does the project challenge or advance current paradigms?  Will the work refine, improve or be a new application of theoretical concepts, approaches, methodologies, instrumentation or intervention?
* **Experimental approach:** Are the overall strategy, methodology and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
* **Likelihood of success**: How likely is the hypothesis to be proven?
* **Impact**: If successful, will the project accelerate the development of therapeutics for neurodegenerative diseases of aging in a significant and sustained way?
* Other as needed

**Additional criteria considered when reviewing Proposals:**

* **Experimental approach**: Are potential problem areas adequately considered and addressed?
* **Development plan** for the therapeutic or tool: What are the steps after this study to continue development if successful?  If unsuccessful?
* **Team and environment**: How well-suited are the team and environment for this work?  Does the work take advantage of unique features of either?
* **Budget and timeline**: Are the proposed budget, milestones and length realistic yet aggressive for the research proposed?
* Other as needed

**Section 6 Additional Information**

Please see the “Details” section below for important additional information about this RFP.

The Foundation welcomes inquiries concerning this RFP. Please contact info@westonneuroscience.ca or (416) 935-4056.

Transformational Request for Proposals on

Neurodegenerative Diseases of Aging - Details

Institutions and individuals affiliated with and applying through or on behalf of institutions (collectively, “Applicants”) should carefully discuss these terms 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.

Any grant provided by the Foundation pursuant to this RFP shall be directed to the institution and not to the individual affiliated with and applying through an institution. Responsibility for the planning, direction, and execution of the proposed project will rest solely with the PI(s).

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.

1. Eligibility of Applicants

The Foundation is only able to accept Letters of Intent (“LOIs” and each an “LOI”) and Proposals (“Proposals” and each a “Proposal”) from institutions (or individuals affiliated with and applying through or on behalf of institutions) that are Canada Revenue Agency qualified donees in Canada. Funds can also be used to support the Canadian portion of collaborations with members from other geographies.

Only researchers at or above the level of Assistant Professor or equivalent are eligible to apply as the Principal Investigator (PI). Collaborators must be at the post-doctoral level or above.

A LOI submitted pursuant to this RFP does not need to be approved by the relevant institution on whose behalf or through which the LOI is being submitted. However, any Proposal submitted pursuant to this RFP must be approved by the institution on whose behalf or through which the Proposal is being submitted.

1. Funding Specifications

**Overall funds**: The Foundation will commit up to $4 million to fund projects selected through this RFP process. Grants are contingent on the receipt of a sufficient number of high quality applications.

**Funds available per project**:

* $500,000 per project per year for up to three years to a maximum of $1,500,000 per project
* Direct costs covered must be appropriate and justifiable for the work proposed
* Each item and its cost must be clearly described in the Proposal budget
* Funds granted cannot be used for travel expenses to scientific conferences/meetings, administrative costs or indirect costs
* The Foundation does not normally fund equipment purchases but may where equipment is necessary for significant progress directly relevant to the proposed project and cannot be funded by any other funding body
* Grants awarded may not be for the full amount requested

**Multiple institutions**: In the event of collaboration between multiple institutions, funds must be paid to the PI-POC’s institution. It is the responsibility of the PI-POC to distribute/manage funds appropriately.

**Full or partial support of projects**: The Foundation can support a full or parts of any project, e.g., the cost of a clinical trial may exceed the per project budget of this program but Applicants may seek partial support for that trial.

**Conditional funding and milestones**: Grants are conditional on grantees meeting certain milestones and providing deliverables including submission of progress reports and participation in Foundation sponsored assessment meetings. Continued support is not automatic and is contingent upon the progress reports being favourably reviewed by the Foundation.

**Supplemental funding**: The Foundation encourages grantees to seek additional funds to further their work once the term of the initial grant has expired. The Foundation has no guaranteed policy for 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 RFPs.

1. 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:

1. was generally known to the public prior to the effective date of this RFP;
2. becomes generally known to the public through no unlawful or unauthorized act by any recipient of Confidential Information; or
3. 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 is 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.

1. Conflicts of Interest

Applicants under this RFP will be excluded from serving on the scientific review committee that reviews their application.

Non-Applicants serving on the scientific review committee may still have a conflict of interest that arises during the grant review process. Any involvement or interest in an application that may reasonably be believed to affect the exercise of independent judgment in relation to the review and evaluation by a member of the scientific review committee of an application must be disclosed immediately in writing to the Foundation.

When a conflict of interest is deemed to be present by the Foundation in its sole discretion, the scientific review committee member will be ineligible to review the LOI and/or Proposal and will be asked to leave the room when the LOI and/or Proposal is discussed during the review process.

Scientific review committee members are also urged to avoid any actions that might give the appearance that a conflict of interest exists, even if the individual believes there may not be an actual conflict of interest.

1. Other

***Liability and Indemnity***

Each Applicant pursuant to this RFP acknowledges and agrees in responding to the RFP that the Applicant shall have no claim against the Foundation, and its respective representatives or affiliates, should such RFP 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 RFP process and its outcome.

The Foundation’s role in grants awarded pursuant to this RFP 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 RFP 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 RFP, including discoveries, is not the property of the Foundation.

The Foundation does require 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 the open access scientific literature or other forms of publication that are readily available to the research community, unless such publication will jeopardize the Applicant’s right to secure patents or copyrights necessary to protect the Applicant’s ownership. 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 2 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.

The Foundation expects all tools or reagents (i) funded by and (ii) that result from funded projects will be made readily available to the community for research purposes either freely or at reasonable prices. The Foundation may let the public know of these tools or reagents so other researchers know they are available.

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

***Application Process***

The Foundation is unable to provide feedback to Applicants not invited to submit a Proposal.

Unsuccessful Proposals will receive written feedback from the scientific review committee. No appeal process is currently available.

Contracting must be completed within six weeks of notification of selection as a grantee. If contracting is not completed at this point, the Foundation reserves the right to cancel the grant.

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

***Milestones and Assessment***

In addition to meeting milestones, the grantees must complete the following if the grant is awarded:

* + *Progress Reports*. A progress report including a written report with budget, telephone discussion with the PI-POC and, if requested by the Foundation, data underlying your research (solely for use in assessing progress), is due every six months unless otherwise notified by the Foundation. Templates for the progress report will be provided by the Foundation.
	+ *Assessment Meeting*. At least one PI on the grant must attend an assessment meeting to report on the progress of the project and have the opportunity to meet other funded researchers. Assessment meetings will be held once a year unless otherwise notified by the Foundation. Additional key personnel may also attend if approved by the Foundation. Travel expenses to required assessment meetings will be provided by the Foundation.
* *Foundation Member Visits.* With prior consent of the PI, Foundation members may wish to visit researchers to see project work underway. These visits are not mandatory, and the Foundation hopes that the 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 (i) recoverable by, and subject to restitution by the grantees, to the Foundation and (ii) may be cause for immediate termination of funding by the Foundation. Any funding provided beyond what is needed for the agreed upon research must be returned to the Foundation at the completion of the research funded by the Foundation.

Transformational Letter of Intent – Cover Page

Project title:

Project key words (up to 10):

1. Category (**bold** all that apply and/or fill in “Other”; can include items from both therapeutic and tool columns):

Tool

* + Animal model
	+ Biomarker
	+ Cell line
	+ Diagnostic
	+ Imaging technique or reagent
	+ Other <please fill in>:

Therapeutic

* + Biologic
	+ Medical device
	+ Small molecule
	+ Surgical intervention
	+ Vaccine
	+ Other <please fill in>:
1. Neurodegenerative diseases of aging impacted (**bold** all that apply):
* Alzheimer’s disease
* Parkinson’s disease
* Dementia with Lewy Bodies
* Frontotemporal dementia
* Amyotrophic lateral sclerosis
* Multiple system atrophy
* Mild cognitive impairment as prodromal to one of the above diseases
1. Phase (**bold** all that apply and/or fill in “Other”): Please note basic/exploratory science is not eligible for this program.
* Preclinical
	+ Target validation
	+ Assay development
	+ Screening and hits to leads
	+ Lead optimization
	+ Studies enabling the submission of an investigational new drug (IND) application (e.g., animal toxicology, safety and efficacy)
* Clinical trials
	+ Phase I
	+ Phase II
	+ Phase III
* Other <please fill in>:

Transformational Letter of Intent – Applicant Details

**Instructions**

For each Principal investigator and Collaborator working on the project, please list his or her primary institution, other affiliated institutions, appointments at these institutions, phone number and email address.

**Principal Investigator – Point of Contact (PI-POC)** - responsible for all correspondence with the Foundation, submitting any information requested by the Foundation, and, if awarded the grant, receiving/managing funds and ensuring a PI attends all assessment meetings.

**Other Principal Investigator(s)** - individual(s) leading the development and execution of the project. There can be more than one PI.

**Collaborator(s)** - someone at a post-doctoral level or above outside the PI(s)’ lab who contributes substantially to the project but is not leading the work.

**Principal Investigator - Point of Contact:**

**Other Principal Investigator(s) (if applicable):**

**Collaborators (if applicable):**

Transformational Letter of Intent – Questions

**Instructions**

Please answer the questions below in 1 (preferable) or a maximum 2 of pages.

In addition, applicants may include a maximum of 1 page of preliminary data, e.g., figures, tables, or references. The scientific review committee will not review more than 1 page of preliminary data.

Please do not includebackground information (e.g., pathology, etiology or incidence/prevalence) of neurodegenerative diseases of aging.

1. **What are the project goals and specific aims?**
2. **What is your experimental plan?**
3. **How will a successful outcome improve your or the field’s development of therapeutics or diagnostics for neurodegenerative diseases of aging?**