



PROGRAM DETAILS

Novel Biomarkers 2017

Background

The Selfridges Group Foundation with the Weston Brain Institute (the “Institute”) supports neuroscience research that accelerates the development of therapeutics for neurodegenerative diseases of aging. To help achieve this, the Institute addresses gaps and inefficiencies in the funding market by supporting high-risk, high-reward translational projects, while leveraging world-class business and scientific expertise in a fast and flexible granting process.

The Institute was founded by The W. Garfield Weston Foundation, which supports the Institute’s Canadian programs. The Institute’s programs in the UK, Ireland and the Netherlands are supported by The Selfridges Group Foundation. Selfridges Group consists of Brown Thomas and Arnotts in Ireland, Holt Renfrew in Canada, Selfridges in the UK and de Bijenkorf in the Netherlands.

Neurodegenerative diseases of aging are among the least understood and most undertreated diseases today. Diseases such as Alzheimer’s and Parkinson’s are placing a large an increasing burden on society. If ignored, the social and economic costs to manage these diseases will rise significantly within a generation.

Meeting this challenge requires pioneering approaches to accelerating treatments. The Novel Biomarkers 2017 program was launched to support high-risk, high-reward, translational research on novel biomarkers.

Important things to know about the Institute:

- **We do not fund basic (also known as fundamental) research.** We only fund translational research.
- **Funds are provided contingent on meeting milestones.** If your project is awarded, funds are provided in tranches when experimental milestones are successfully completed.
- **Our application process is interactive.** You will likely receive feedback on your applications and may be asked to make modifications. We also encourage you to reach out if you have questions about our funding programs.
- **Many projects are declined at the Letter of Intent (LOI) stage.** 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 30-100%.
- **We provide more than funding.** Our grantees may also benefit from things like the expert advice of our scientific advisors, industry exposure, networking, and international collaboration opportunities.

Institute definitions:

A full list of our definitions is available on our website.

The Weston Brain Institute welcomes any inquiries concerning this program announcement. Please contact Rachel Reeve. Research Program Specialist at rachel.reeve@weston.ca or +1 416-965-5656.

- **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 these 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).
- **Translational research:** Applied research towards developing therapeutics for the prevention and/or treatment of human disease. For example, for small molecule drug development, this includes target validation to phase IIa clinical trials.
- **Tool:** An item that accelerates development of therapeutics, e.g., animal model, imaging techniques or reagents, biomarkers, or diagnostics.
 - o Tools that will expand our knowledge of basic research may be important for the field, but the Institute will only value the tool for its immediate impact on translational research.
 - o A strong rationale and hypothesis must be provided for the development of a tool, including how the tool will have a direct impact on translational research as defined by the Institute (i.e., target validation to phase IIa clinical trials).
 - o Projects covering only the discovery/identification of a tool are out of scope.
- **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; but not complementary approaches. Therapeutics can be for symptomatic relief, disease modification, or prevention.
- **Complementary approaches:** Approaches to treating disease or maintaining health that are not therapeutics as listed below. Examples include exercise, diet, acupuncture, nutritional supplements, and enriched environments. These are not funded by the Institute.
- **Clinical samples/data:** Patient-derived specimens/resources or data, e.g., tissue, fluid, and imaging scans.
- **Novel biomarkers:** Underfunded and/or less studied biomarkers.

Section 1 **Scope**

The Novel Biomarkers 2017 program funds testing of understudied and/or underfunded biomarkers in clinical samples/data or patients to accelerate the development of therapeutics for neurodegenerative diseases of aging, as defined by the Institute. Candidate biomarkers should have pilot data to justify testing in clinical samples/data or patients. Novelty of the biomarker will be a criterion for adjudicating applications.

Biomarkers should be for disease diagnosis, prognosis, for stratification to clinical trials or to predict response to therapies. 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, grip strength, and cognitive tests). Genetic determinants and genetic predispositions are not in scope. Biomarker discovery and unbiased screening approaches are not considered within the scope of this program.

Use of existing clinical samples/data where possible is strongly preferred. A letter of support from the samples/data provider indicating permission to use the relevant samples/data will be required in advance of funding. If already available, applicants should provide this letter at the Proposal stage. If the

project will not rely on existing samples/data, applicant must provide justification for the need and feasibility to collect the required samples/data and protocols for collection and quality testing in the Proposal. Any samples used should have proper collection/storage procedures and adequate donor data, for example from biobanks or imaging banks.

The Institute encourages applicants to contact us with any questions regarding the program, including whether a potential idea is in scope.

Section 2 Funding Specifications

Total funding: The Institute will commit up to £1 million to fund projects selected through this Program. Grants are contingent on the receipt of a sufficient number of high quality applications.

Funds available per project:

- Up to £333,000 paid to an institution in the UK or €390,000 paid to an institution in Ireland, over up to 3 years. Projects are encouraged to use existing samples/data and these projects will likely require less funding.
- Funds will be granted only for direct costs that are appropriate and justifiable for the work proposed.
- Funds cannot be used for equipment purchases, computer purchases, administrative costs or indirect costs, unless prior written approval from the Institute has been obtained.
- Funds cannot be used as salary support for individuals who already receive a salary from their institution.
- Travel expenses to scientific conferences/meetings to present work funded by the Institute can be included in the budget.
- Each item and its cost must be clearly described in the budget (provided at the Proposal stage only).
- The amount granted may not be for the full amount requested.
- Up to 35% of the funds can be used to support international collaborations or bring unique international resources from outside the UK or Ireland.
- Funds may be used to support the Ireland and/or UK portion of international collaborations.

Any grant provided by the Institute pursuant to this Program shall be directed to the institution and not to any individual. Responsibility for the planning, direction, and execution of the proposed project will rest solely with the Applicants. If the funded project has the potential for significant commercial success, in the grant agreement, the Institute may request, upon significant commercial success, repayment of grant funds to be used for further research funding.

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 Institute can support a full project or parts of a project. If the application is for part of a larger project, the criteria for granting will be applied only to the part of the project proposed. Applicants should make clear what part of the larger project the Institute funding would support.

Conditional funding and milestones: Grants are conditional on grantees meeting pre-determined milestones and providing deliverables, including submission of progress reports and participation in Institute sponsored Research Days. Continued support is not automatic and is contingent upon the grant progress being favourably reviewed by the Institute.

Supplemental funding: The Institute encourages grantees to seek additional funds to further their work. The Institute has no guaranteed policy for renewal or continuation of grants. The Institute may, at its discretion, seek to further support clearly successful projects.

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 Institute. Selected applicants will then be invited to submit a Proposal.

The LOI stage of the application process is a significant stage of evaluation. Typically, only a small proportion of applicants are invited to submit full proposals, and of those, many will be funded. This ensures LOIs are easy to submit so that promising ideas are not missed, while ensuring applicants taking the time to write full Proposals have a very good chance of being funded. In past programs, ~10-20% of applicants submitting LOIs were invited to submit Proposals, and at least 30% of submitted Proposals were funded.

Each LOI will be peer reviewed by a scientific review committee. Applicants whose LOIs meet the rigorous review criteria will be invited to submit a Proposal. Budgets are only required at the Proposal phase. Proposal instructions and feedback from our scientific review committee will be forwarded along with the invitation. Complete Proposals will be peer reviewed by a scientific review committee. No appeal process is currently available.

The grant agreement must be completed within 6 weeks of notification of selection; otherwise the Institute reserves the right to cancel the grant.

Section 4 Review Criteria

Criteria considered when reviewing LOIs:

- **Innovation:** How novel is the work and biomarker under study?
- **Experimental approach:** Are the overall strategy, methodology and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Is the availability and quality of clinical samples/data or patients sufficient?
- **Likelihood of success:** How likely is this project to succeed (in advancing development of a new biomarker for disease diagnosis and prognosis, for stratification to clinical trials or to predict response to therapies)?
- **Impact:** If successful, to what extent will this project accelerate the development of therapeutics for neurodegenerative diseases of aging?
- **Fit:** Is the project, including its scale and scope, appropriate for this program?
- Other as needed.

Additional criteria considered when reviewing Proposals:

- **Experimental approach:** Are potential problem areas adequately considered and addressed? Is the plan to obtain clinical samples/data or patients feasible?
- **Development plan:** What are the steps after this study to continue development of this biomarker if successful?
- **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? These are secondary considerations after the other criteria have been weighed.
- Other as needed.

Section 5 Eligibility of Applicants

For this program, the Institute is able to accept applications from individuals affiliated with and applying through or on behalf of institutions located in the United Kingdom (UK) or the Republic of Ireland (Ireland) that are UK-registered charities, or are registered with the Charities Regulatory Authority in Ireland.

The Institute may also be able to accept applications from individuals affiliated with and applying through or on behalf of qualified institutions in Ireland or the UK meeting the public benefit requirement towards research in neurodegenerative diseases of aging. To confirm eligibility of these institutions before applying, please contact Crystal Braganza (crystal.braganza@weston.ca, +1-416-965-5695).

Principal Applicants must be at or above the level of Lecturer (Assistant Professor, or equivalent) and hold an appointment at the institution from which they are applying. Each applicant may submit one LOI as Principal Applicant, and may appear as a Co-Applicant or Collaborator on an unlimited number of applications.

Principal Applicants must be either a UK-based researcher working in the UK at least 30% of the time, or an Ireland-based researcher working in Ireland at least 30% of the time.

Proposals (but not LOIs) submitted to this Program must be approved by the institution on whose behalf or through which the Proposal is being submitted.

Section 6 Reports and Assessments

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

- **Milestone Reports.** Payments are tied to successful completion of project milestones mutually agreed upon by the Applicants and the Institute. A milestone report is due prior to each scheduled payment being made.
- **Progress Reports.** A progress report includes a written report with budget and, if requested by the Institute, a telephone discussion with the Principal Applicant and/or data underlying the

research (solely for use in assessing progress).

- **Research Day.** At least one Applicant on the grant must attend Research Day(s) to report on the progress of the project and have the opportunity to meet other funded researchers. Applicants will attend one Research Day per year, unless otherwise notified by the Institute. Additional key personnel may also attend if approved by the Institute. Travel expenses to Research Days will be covered by the Institute and should not be included in the budget.
- **Foundation Member Visits.** With prior consent of Applicants, Foundation members may wish to visit researchers to see project work underway. These visits are not mandatory, and the Institute hopes that grantees will welcome this opportunity.
- **Financial Accountability.** Grantees are expected to account for the moneys expended under any Institute 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 Institute and may be cause for immediate termination of funding. Any funding provided beyond what is needed for the agreed upon research must be returned to the Institute.

Section 7 Confidentiality

The Institute 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 Institute assessments. All Confidential Information will be used by the Institute 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 Institute or its scientific review committee without reference to the Confidential Information.

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

Section 8 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 (“Proposals” and each a “Proposal”) does not bind either the Institute 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 Institute reserves the right to

alter, delete, or add additional terms in the grant agreement between the successful Applicants and the Institute.

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

Section 9 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 Institute, and its respective representatives, related companies or affiliates, should such Program response be unsuccessful for any reason. Each Applicant hereby remises and releases the Institute, its representatives and affiliates, from any cause of action, complaint, or claim in connection with the RFA process and its outcome.

The Institute's role in grants awarded pursuant to this Program is that of a funder. The Institute is not the sponsor of funded projects. As such, the Institute will not assume any liability associated with funded projects and each Applicant who is ultimately awarded a grant pursuant to this Program releases the Institute from any and all liability with respect thereto and further indemnifies the Institute, 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 Institute acknowledges that any intellectual property ("IP") that arises from research funded through this Program, including discoveries, is not the property of the Institute.

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

Publication and Sharing Policy

The Institute 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. Grantees will advise the Institute of the details of any such publication (journal, publication date, etc.), as soon as the information is known.

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 Institute.



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 Institute, in a manner proportionate to the contribution of the Institute. Any other use of the Institute's intellectual property, including its name, logo or trademark requires prior written permission of the Institute.

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 3 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 these rights have been secured. The Institute may let the public know of these tools or reagents so other researchers know they are available.

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

The Institute requires any clinical trial awarded under any of its funding programs be registered with clinicaltrials.gov, [PD Trials.org](http://PDTrials.org), EU Clinical Trials Register or other appropriate public registry.