

## Weston Family Microbiome Initiative

### NEW FUNDING ANNOUNCEMENT

### WFMI Proof-of-Principle 2019 – Prebiotic Strategies

|                                  |   |                      |
|----------------------------------|---|----------------------|
| Information Webinars:            | January 29 <sup>th</sup> , 30 <sup>th</sup> 2019 @1:00 p.m. EDT | Funds: \$150,000 CAD |
| Letter of Intent (LOI) Deadline: | February 11 <sup>th</sup> , 2019 2:00 p.m. EDT                  | Duration: <24 Months |
| Full Proposal Deadline:          | April 11 <sup>th</sup> , 2019 2:00 p.m. EDT                     |                      |
| Anticipated Award Notice:        | May, 2019   |                      |

*\*The Foundation may, within its sole discretion, change these dates*

### Program Information

The W. Garfield Weston Foundation is pleased to announce new programming in support of Canadian research efforts on the human microbiome. The **Weston Family Microbiome Initiative** will provide funding for innovative academic projects in an effort to:

- 1) Advance the application of the microbiome in improving human health
- 2) Foster greater collaboration within the Canadian research community
- 3) Position Canada as a global leader in the field of microbiome research

This **Proof-of-Principle** program will provide research grants of up to \$150,000 over 24 months to support high-impact projects that seek to develop novel **microbiome-based therapies**.

Eligible Projects will:

- Establish an innovative line of **translational research** and provide **proof-of-principle** evidence in support of new therapeutic or health applications of the microbiome (i.e. intervention or preventative strategies).
- Catalyze longer-term bench-to-bedside initiatives that seek to move discoveries through to clinical application.
- Focus on improving health by influencing the microbiome through prebiotic strategies.

### Application Process

There are two stages to this application: Letters of Intent (LOI) and Proposals. Details of the LOI stage and a mandatory template for submission can be found in the accompanying document and on the Initiative website. **Applicants may submit a maximum of one application, when acting as lead applicant, to the program.** Applicants invited to submit a full Proposal will receive instructions and reviewer feedback at the time of invitation. All applications will be rigorously peer reviewed by a scientific advisory committee. LOIs and Proposals should be submitted to [geordie.stewart@westonfoundation.ca](mailto:geordie.stewart@westonfoundation.ca). Please refer to the accompanying “Program Details” section for important information on the Program.

## Weston Family Microbiome Initiative

### About the Foundation

For three generations, The W. Garfield Weston Foundation has pursued its mission to enhance and enrich the lives of Canadians. With a focus on medical research, the environment, and education, the Foundation aims to catalyze inquiry and innovation to bring about long-term change. As the Foundation marks its 60<sup>th</sup> anniversary, it 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.

The Foundation has a long history of supporting medical research, from funding the Banting and Best Institute in the 1960s to the establishment of the Weston Brain Institute, a program dedicated to supporting the development of therapeutics for neurodegenerative diseases. The Foundation's newest program, the Weston Family Microbiome Initiative, continues this long-standing commitment to health research and supporting Canadian science.

### The Weston Family Microbiome Initiative

The human body is host to trillions of microbes. A wealth of research suggests that these organisms play important roles in bodily function, health and disease. For example, the communities of bacteria living in the gut are thought to have a profound bearing on nutrition and are suspected to influence numerous and varied diseases, including gastrointestinal, immunological, cardiac and neurological afflictions. For these reasons the microbiome represents a promising avenue for new strategies in disease treatment and preventative health. The success of fecal microbial transplants in treating infections caused by *Clostridium difficile* underscores the potential for new microbe-based therapies. However, these successes notwithstanding, to date there are few instances where the microbiome has been successfully leveraged to improve health. The Weston Family Microbiome Initiative (WFMI) will support high-impact Canadian research that strives to develop new therapies that harness the microbiome to improve human health and quality of life.

#### Important things to know about the WFMI:

- We do not fund basic or fundamental research. We fund translational science that drives towards the application of knowledge.
- Funds are provided in tranches based on the successful completion of milestones.
- The application process is interactive. Applicants are encouraged to connect with the Foundation to discuss their proposals. Applicants will receive feedback and recommendations from reviewers, and if merited, will be given an opportunity to implement changes.

## Weston Family Microbiome Initiative

### Program Details

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.

#### 1. Project Scope

The Proof-of-Principle Program will provide funding to innovative projects that seek to leverage the microbiome to deliver new therapies, interventions or preventative strategies for improving health. This includes **modifying, manipulating or exploiting** the microbiome to confer health benefits or treat diseases.

For this program, projects will focus on **prebiotic strategies** using *non-viable substrates* that confer a health benefit on the host associated with modulation of, or influence on, the microbiota. This excludes probiotics and other live microbial therapeutics. Eligible projects include those that focus on:

#### Prebiotics

The Foundation defines a Prebiotic as ‘a substrate that is selectively utilized by host microorganisms conferring a health benefit.’ This definition, adopted from the 2017 consensus statement by the International Scientific Association for Probiotics and Prebiotics (ISAPP), allows for substrates acting at numerous microbially colonized body sites (i.e. gut, skin, mouth, etc.) and includes both carbohydrate (i.e. traditional prebiotic fibres) and non-carbohydrate substances (i.e. polyphenols).

#### Other Non-Viable Dietary Components

For this call, the Foundation will also consider projects focused on other non-viable dietary components that confer a benefit on the host associated with modulation of microbiota structure and/or function, but that do not strictly meet the ISAAP definition of a Prebiotic (as above). Once again, this excludes probiotics and other live microbial therapeutics.

Research Projects must be translational in nature and can be at any point along the development pathway (discovery, pre-clinical, clinical, etc.). The foundation defines **translational research** as applied research towards developing therapies for the prevention and/or treatment of human disease. Applicants are asked to carefully consider the suitability of proposed methods in developing applications for the human microbiome. The use of human study, animal models, *in vitro*, or *ex vivo* experiments should be justified with respect to the goals of the project.

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### Eligibility

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.

The principal applicants must be at or above the level of assistant professor or equivalent at a CRA-qualified donee in Canada. Projects must align with the scope of the Program as outlined below. Each Principal Applicant is permitted to submit a maximum of one application to each stream of the Program. An LOI submitted pursuant to this Program 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 Program must be approved by the institution on whose behalf or through which the Proposal is being submitted.

### 2. Funding Specifications

**Overall funds:** The Foundation will commit up to ~ **\$1,500,000** to projects selected through this program (approximately 10 projects). Grants are contingent on the receipt of a sufficient number of high quality applications. The Foundation reserves the right to expand the funding envelope for either program stream should it deem there to be many high-quality Proposals submitted in this call.

### Project Funding

- Grants will provide up to \$150,000 CAD per project to be used over up to 24 months.
- Funds will be granted only for direct costs that are justifiable for the work proposed.
- Items and cost must be clearly described in the budget of the full Proposal.
- Funds cannot be used for equipment purchases, computer purchases, administrative costs or indirect costs, unless written approval from the Foundation is received.
- The granted funds may deviate from the full amount requested.
- 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).

Any grant provided by the Foundation pursuant to this Program shall be directed to the institution and not to the individual affiliated with and applying through the institution. Responsibility for the planning, direction, and execution of the proposed project will rest solely with the Applicants in collaboration with their respective institution.

**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 can support a full project or a portion of any project, e.g., the cost of a clinical trial may exceed the project budget of this Program but Applicants may seek partial support for that trial. In the case of the latter, applicants should provide proof of the necessary resources to complete the full project.

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**Conditional funding and milestones:** Grants are conditional on grantees meeting pre-determined milestones and providing deliverables, including submission of progress reports and/or participation in Foundation sponsored assessment meetings. Continued support 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 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 and RFAs.

### 3. Information Webinar

The Foundation will host Information Webinars on **January 29<sup>th</sup> and January 30<sup>th</sup>, 2018 at 1 pm EDT**. The Webinar will be hosted through the GoToMeeting web platform. Details will be forwarded to interested applicants in advance of the meeting and can be found on the Initiative website. Applicants are asked to indicate their intention to join the meeting by emailing [geordie.stewart@westonfoundation.ca](mailto:geordie.stewart@westonfoundation.ca) or by signing up at the event page through the Foundation website ([www.westonfoundation.org](http://www.westonfoundation.org)).

### 4. Application Process

The application process consists of two stages: Letters of Intent (LOIs) and Proposals. Applicants must submit a LOI to the Foundation to be considered for Proposal submission to the Program. Each LOI will be reviewed internally by the Foundation and peer reviewed by a scientific advisory committee. Materials should be submitted to [geordie.stewart@westonfoundation.ca](mailto:geordie.stewart@westonfoundation.ca) by the indicated deadline. Applicants are asked to indicate their intent to submit an LOI by email at [geordie.stewart@westonfoundation.ca](mailto:geordie.stewart@westonfoundation.ca).

The LOI stage of the application process is a significant stage of evaluation. It is expected that only a small proportion of applicants will be invited to submit full Proposals, and of those, many will be funded. This ensures that LOIs are easy to submit so that good ideas are not missed, while ensuring that applicants that take the time to write full Proposals have a very good chance of being funded. In past Programs more than 50% of submitted Proposals were funded.

Applicants whose LOIs meet the review criteria and are favourably reviewed will be invited to submit a full Proposal. Proposal instructions and feedback from the scientific review committee will be forwarded along with the invitation. Applicants will be required to obtain and submit relevant institutional signatures at the Proposal stage. Complete Proposals will be peer reviewed by the scientific review committee. 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.

**Weston Family Microbiome Initiative****5. Key Dates**

|                                  |   |
|----------------------------------|---|
| Information Webinars:            | <b>January 29<sup>th</sup>, 30<sup>th</sup>, 2019 1:00 p.m. EDT</b> |
| Letter of Intent (LOI) Deadline: | <b>February 11<sup>th</sup>, 2019 2:00 p.m. EDT</b>                 |
| Full Proposal Deadline:          | <b>April 11<sup>th</sup>, 2019 2:00 pm EDT</b>                      |
| Anticipated Award Notification:  | <b>May, 2019</b>  |

**6. Review Criteria**

The following criteria will be considered in reviewing LOIs and Proposals. At the **LOI stage**, the primary focus of review will be the **scientific idea** itself. At the Proposal stage, reviewers will place increased consideration on the strength of the methodology, milestones and contingencies, budgeting, and the suitability of the project team and research environment.

**LOI Stage**

**Innovation:** Does the project challenge or significantly expand current paradigms in the field? Will the work refine, improve or be a new application of existing knowledge, technologies or methods? Does the project demonstrate potential to lead to important novel applications?

**Potential for Impact:** If successful, will the project accelerate the development and application of new technologies or approaches for the prevention and/or treatment of human disease? Will the work performed pave the way for more advanced applied therapeutic studies? If unsuccessful, will the insights gained make a significant contribution to the field or foster a new line of research? How will the project impact the health of Canadians near-term/long-term?

**Likelihood of Success:** How likely is it that the stated goals will be achieved? Are the project goals and hypotheses grounded in the state of the field and strength of the team?

**Experimental Approach:** Does the project propose reasonable, testable and clear hypotheses? Are the proposed strategies and methodologies well-reasoned and appropriate for the work being undertaken?

**Additional Criteria Considered at the Proposal Stage**

**Development Plan:** If the project is successful, what are the next steps needed to advance the application of the discovery? What additional resources (financing, infrastructure, collaborators) will be needed?

**Experimental Approach:** Are the methodologies described in sufficient detail so as to present a compelling action plan for addressing the proposed hypotheses? Are methods well established and have they been demonstrated effective in the scientific literature? If not, are the appropriate experiments in place to validate new methods/processes? Are there alternative methodologies that should be considered based on effectiveness or cost? Have limitations been considered?

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**Team and Resources:** Does the project team have the capabilities and capacity to reliably execute the proposed experiments and analyses? Does the proposed project capitalize on any unique resources or competencies?

**Budget and Timeline:** Are the proposed budget, milestones and length realistic yet aggressive for the proposed research?

**Milestones:** Has the team identified critical milestones and relevant contingencies? Does the applicant indicate a well-thought out strategy with go/no-go check-points that will help mitigate risk? Have potential problem areas been adequately considered and addressed? What are next steps if work is unsuccessful?

### 7. Regulatory and Ethics Approval

It is highly recommended that applicants initiate the process of seeking Health Canada Approval for studies, where required, at the Proposal stage or earlier. Obtaining necessary regulatory approval can introduce significant lag into a research project and be a major hurdle to success. While not essential for funding approval, the review panels look favourably upon those projects that proactively seek to understand and address necessary regulatory approvals (Health Canada, ethics) in advance of the launch of the project.

### 8. Power Calculations

Applicants should provide appropriate power calculations to justify project scale and demonstrate statistical significance of proposed studies and prospective outcomes (as necessary).

### 9. Reports and Assessments

Grantees are responsible for the completion of the following if a grant is awarded:

- *Milestones.* Proposed Projects must include clear milestones that guide the continuation of research (go/no-go). Pre-determined milestones, as agreed upon by the Applicants and the Foundation, will be used to determine reporting dates and the distribution of payment tranches. A brief milestone report will be required in advance of payment.
- *Progress Reports.* A progress report including a brief written report with budget, telephone discussion with the Principal Applicant and, if requested by the Foundation, data underlying the research (solely for use in assessing progress), is due every six months unless otherwise notified by the Foundation. Submission dates and reporting frequency will be linked to project milestones and the nature of the research, as agreed upon by the Applicants and Foundation. As this is a pilot program, the Foundation is eager to connect with researchers regarding their progress, successes and challenges. The Foundation kindly invites Grantees to take a proactive approach to communication throughout the Project.



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- *Assessment Meeting.* The Foundation, at its discretion, may require at least one Applicant on the grant to 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 covered by the Foundation per Foundation guidelines.
- *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 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 (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.

### 10. 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 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.

Participating scientific reviewers will be subject to the Foundation’s standard non-disclosure agreement for such engagements.



## Weston Family Microbiome Initiative

### 11. 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 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 RFA process and its outcome.

The Foundation's role in grants awarded pursuant to this Program is that of a funder. It is not the sponsor of funded projects. 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 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 that all tools/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/reagents so researchers know they are available.

The Foundation requires any clinical trial awarded under any of its funding programs be registered with [clinicaltrials.gov](http://clinicaltrials.gov), [PDTrials.org](http://PDTrials.org), or other appropriate public registries.