

## Weston Family Microbiome Initiative

### NEW FUNDING ANNOUNCEMENT

#### WFMI Catalyst 2020 – Microbiome Innovations

Information Webinars:	Oct. 2 <sup>nd</sup> , 13 <sup>th</sup> , 2020 1:00 PM	Funds: \$450,000 CAD
Letter of Intent (LOI) Deadline:	Rolling, final submission Nov. 30, 2020	Duration: <36 Months
Full Proposal Deadline:	Rolling (5 week period for submission)	
Anticipated Award Notice:	Rolling	

*\*The Foundation may, within its 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 **Catalyst** program will provide research grants of up to \$450,000 over up to 36 months to support highly innovative scientific research seeking to apply the microbiome in improving human health.

Eligible Projects will:

- Conduct **translational research and development** focused on delivering new microbiome-based health strategies or **implementation studies** focused on the application and adoption of microbiome-based health strategies.
- Strive to develop a new recommendation, intervention, technology, system or preventative strategy that improves health by leveraging the microbiome.
- Propose *radical innovations*, which generate novel ideas, technologies, or approaches.

### Application Process

There are three stages to this application: Letters of Intent (LOI), Proposals and a Live Review. 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.** Applicants invited to submit a full Proposal and attend the Live Review 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 [microbiome@westonfoundation.ca](mailto:microbiome@westonfoundation.ca). Please refer to the accompanying “Program Details” section for important information on the Program.

THE W. GARFIELD WESTON  
FOUNDATION  
**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 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 warranted, will be given an opportunity to implement changes.

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### 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 Catalyst program provides the resources and timeline to enable **early-career researchers** to take **greater risks**, propose big ideas, address challenging questions and accelerate clinical testing and demonstration. Eligible projects will seek to leverage the microbiome to deliver new therapies, interventions or preventative strategies for improving health. This includes **diagnosing, modifying, manipulating** or **exploiting** the microbiome to confer health benefits or treat diseases.

Competitive projects will:

- Develop a **new microbiome intervention or preventative strategy** for improving health; OR
- Definitively **address a major knowledge gap** and provide a new path towards future intervention or preventative strategies; OR
- Identify new strategies or technologies to **implement and drive the adoption** of microbiome-oriented interventions in the clinic or market.

The Foundation will consider all dimensions of human health for which there is compelling evidence of a microbiome linkage and potential to significantly benefit Canadians. Priority will be given to those projects aligned with Microbiome Initiative’s strategic priorities, which currently include **immunity and infection, brain health, and lifestyle interventions contributing to healthy aging**.

In addition, emphasis will be placed on driving innovation in **prebiotics**, which have been dominated by incremental clinical studies in a narrow range of diseases (i.e. testing known prebiotics for treating obesity). Innovations suitable for this program could include:

- Novel prebiotics
- Prebiotic interventions in new disease areas
- Combination therapies and prebiotic/probiotic synergy
- Personalization for improved prebiotic efficacy

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Applicants are encouraged to consult with the Foundation should they have any questions regarding the eligibility of their proposed project.

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.

Please refer to the definitions section at the end of this document for additional clarity on scope and eligibility.

### Applicant Eligibility

This program provides funding for **early-career** (< 5 years active) Canadian researchers. Applicants must be at the level of an assistant professor or higher for the duration of the award. Post-doctoral fellows or equivalent expecting to transition to faculty positions within the next 6 months are encouraged to apply. However, a full-time faculty position will be an essential condition of funding. Equivalent positions will be considered on a case-by-case basis.

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 this 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 ~ **\$1,800,000** to projects selected through this program (approximately 4 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 should it deem there to be many high-quality Proposals submitted in this call.

### Project Funding

- Grants will provide up to \$450,000 CAD per project to be used over up to 36 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.

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- Funds cannot be used for equipment purchases, computer purchases, administrative costs, or indirect costs, unless written approval from the Foundation is received.
- Funds cannot be used for institutional overhead.
- 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.
- Items and 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.

**Conditional funding and milestones:** Grants are conditional on grantee progress, which includes 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 these 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 **October 2<sup>nd</sup> & October 13<sup>th</sup>, 2020 at 1 PM EST**. 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 [microbiome@westonfoundation.ca](mailto:microbiome@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 three stages: Letter of Intent (LOI), Proposal, and Live Review. 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 [microbiome@westonfoundation.ca](mailto:microbiome@westonfoundation.ca) by the indicated

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deadline. Applicants are asked to indicate their intent to submit an LOI by email at [microbiome@westonfoundation.ca](mailto:microbiome@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. Unsuccessful Proposals will receive written feedback from the scientific review committee. No appeal process is currently available.

Applicants whose Proposals meet the review criteria, and are favourably reviewed, will be invited to give a brief presentation outlining their full Proposal and research strategy to a scientific review group. Presentation instructions and feedback from the scientific review committee will be forwarded along with the invitation. This presentation will be followed by a live, in-person review, where applicants have an opportunity to respond to the critiques and suggestions of the review panel. The aim of this review is to identify critical weaknesses and opportunities for improvement within the proposed project towards iteratively strengthening the research plan. Reviewers are encouraged to be very thorough in their assessment of the project, and applicants should be prepared to address concerns in detail. Following the presentation, reviewers will deliberate for several days in conjunction with the Foundation Board to identify those projects that warrant support through this program. Invitation to the Presentation stage does not bind either the Foundation or the Applicants by any commitment to provide or receive funding, respectively.

All reviewers are under an NDA with the Foundation and must declare any potential conflicts of interest prior to agreeing to participate in the review process. Likewise, applicants will have an opportunity to identify any potential conflicts of interest within the research community as well as provide a reviewer exclusion list. Exclusions will be permitted where there is a clear instance of reviewers being competitive with the applicant. The Foundation cannot guarantee it will be able to honour every exclusion request, however, it will take a ‘best-efforts’ approach to ensure justified exclusions are adequately considered. Applicants will be made aware of the review panel in advance of their presentation session.

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.

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### 5. Key Dates

Information Webinars:	<b>Sep 29<sup>th</sup>, Oct 13<sup>th</sup> 2020 1:00 p.m. EST</b>
Letter of Intent (LOI) Deadline:	<b>Rolling, final submission Nov. 30, 2020</b>
Full Proposal Deadline:	<b>Rolling (5 week period for submission)</b>
Anticipated Award Notification:	<b>Rolling</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 and the strength of the applicant. 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 advance current paradigms? Will the work refine, improve or be a new application of theoretical concepts, approaches, methodologies, instrumentation or intervention?

**Potential for Impact:** If successful, will the project accelerate the application of the microbiome to improving health? What will be the long-term impact of success on both the scientific community as well as public health? Will it set up the applicant for continued success in microbiome research?

**Principal Applicant:** Has the applicant demonstrated scientific excellence and aptitude in their previous training or early career? Are they likely to deliver on this project and play a significant role in the advancement of the field?

#### The Proposal Stage

Additional criteria considered at the Proposal and Live Review stages include:

**Experimental approach:** This will include assessment of the proposed methodologies, disciplines and required expertise to execute the research plan. Have gaps been identified and problem areas fully considered? Is the appropriate infrastructure available.

**Development plan:** If the project is successful, what are the next steps in development and advancement? Do the applicants display the capacity and commitment to further research beyond the lab? Have they critically considered the potential regulatory, market, and legal barriers to translation and identified significant risk and mitigation strategies?



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**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 (likelihood that the project cannot be completed) been addressed as much as is reasonable?

**Team and environment:** How well-suited are the team and environment for this work? Does the work take advantage of unique features of either? Has the applicant identified and addressed potential gaps in their team?

**Budget and timeline:** Are the proposed budgets, milestones and length realistic yet aggressive for the research proposed? These are secondary considerations after the other criteria have been weighed.

**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 12 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



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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.

- *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.

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### 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](https://clinicaltrials.gov), [PDTrials.org](https://pdttrials.org), or other appropriate public registries.

## 12. Foundation Definitions

### Early-Career Researchers

Early-Career Researchers (ECRs) are those researchers who have been professionally active for less than 5 years and will operate at the level of assistant professor or higher during the tenure of the award.

### Translational Research

The Foundation defines **translational research** as applied research towards developing therapies for the prevention and/or treatment of human disease.

### Implementation Research

The Foundation defines **implementation research** to include research and initiatives that seek to identify, test and deploy established strategies for improving health, for which some evidence of efficacy already exists. This research strives to find approaches for driving adoption of an intervention or recommendation that positively influences health through the microbiome.

### Lifestyle Approaches

The Foundation defines ‘lifestyle approaches’ as modifiable habits, inputs and ways of life that can influence overall health and well-being. Within the context of this call, the Foundation will consider lifestyle approaches including diet and nutrition, exercise and activity, sleep, stress, amongst others.

### Radical Innovation

The Catalyst program places emphasis on *radical innovation*, which generates wholly new ideas or approaches. Such research should drive the development of disruptive ideas and technologies, apply existing technologies in novel ways, or challenge prevailing thinking on therapy and health.

### Immunity and Infection

Infection and Immunity refers to function and role of the immune system in physiology and health. This can include, but is not limited to, prevention and/or response to infection or specific disease states, regulation and control of the immune system, the role of immunity in off-target or chronic inflammation, the developing and or aging immune system, etc.

### Brain Health

An individual’s optimal level of cognitive well-being that is equal to or greater than the normal cognitive aging process and is free of brain diseases/conditions (e.g., neurodegenerative disease of aging).