Weston Family Foundation

Weston Family Microbiome Initiative
Proof-of-Principle 2025 Program

Microbiome-Based Interventions

Investigating impactful interventions to modulate the microbiome, improve health outcomes, and enhance therapeutic response

Important Dates*

Information Webinar	May 1st and May 6th at 2:00 PM EST
Letter of Intent (LOI) Deadline	June 2nd at 2:00 PM EST
Full Proposal Deadline	August 15th at 2:00 PM EST
Anticipated Award Notice	October 2025

**Dates subject to change*

Background

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

The Foundation takes a leadership role in tackling large problems, in both health and landscapes, that are under-addressed. One of these areas is the human microbiome. 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.

Today, the Weston Family Foundation, through its Weston Family Microbiome Initiative, is pleased to announce a new round of its Proof-of-Principle programming in support of Canadian research efforts on the human microbiome. This program will provide funding to support innovative and scalable projects that:

1) Advance the real-world 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

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4) Demonstrate a convincing ability and aptitude to scale beyond the laboratory setting

The program provides research grants of **up to $300,000 over a maximum of 30 months** to support high-impact, scalable projects that use **microbiome-based interventions to modulate the microbiome, enhance therapeutic responses, or improve health outcomes.** Eligible projects must demonstrate mechanistic pathways for how interventions impact specific disease states or responses to treatments.

Stream 1: $300k – Projects involving active patient engagement and testing.
Stream 2: $200k – Projects not working with patients (e.g. biobanked samples, animal studies, *in vitro*/*ex vivo* experiments).

Important things to know about the Foundation:

- **Focus is on translational research.**
- **Funds are provided contingent on meeting milestones.** If your project is awarded, funds will be provided in tranches when milestones are completed.
- **We focus on scalability.** Projects that demonstrate success and scalability towards real-world implementation or application will be prioritized and considered for continued support by the Foundation beyond this program.
- **Our 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.
- **Applicants apply with a Letter of Intent (LOI), which will be peer-reviewed. Successful LOIs are invited to submit a full proposal and are expected to address reviewer's comments. Historically, ~35% of LOIs go on to the full proposal stage, after which ~60% of full proposals are awarded.**
- **We provide more than funding. Our grantees may also benefit from opportunities such as expert advice from our scientific advisors, industry exposure, networking, and international collaboration opportunities.**

Institutions and individuals affiliated with and applying through or on behalf of institutions (collectively, "Applicants") should carefully discuss the Program announcement and the terms of this document with the appropriate office at their institution before submitting an application. The submission of an LOI or a Proposal does not bind either the Foundation or the Applicants by any commitment to provide or receive funding, respectively.

Successful Applicants will be required to agree to terms substantially similar to those contained in this document and the Foundation reserves the right to alter, delete or add

additional terms in the Grant Agreement between the successful Applicants and the Foundation.
The Foundation reserves the right to accept or reject any or all applications at its discretion and to negotiate the terms of the specific grant agreement with Applicants.
The Foundation, at its sole discretion, may change the timeline of the application process.

Section 1: Scope and Other Project Considerations

The Proof-of-Principle 2025 Program provides funding to innovative and scalable projects that leverage the microbiome to deliver new interventions for improving health in a real-world context. This includes modifying, manipulating, or exploiting the microbiome to confer health benefits or treat diseases impacting Canadians.

For this iteration, projects must be **translational** and identify, validate, or investigate microbiome-based interventions with high potential to treat disease or enhance therapeutic response. The Foundation will consider all potential disease areas with a demonstrated relevance to Canadians that show strong evidence linking the microbiome. However, priority will be on projects that focus on promoting healthy aging.

Eligible projects will be in one of the three priority areas:

- ***Intervention*:** Developing novel therapeutic microbiome-based interventions for treating disease or **improving health outcomes** in a population.
    - E.g., Administer a probiotic as an intervention specifically focused on a microbiome target implicated in irritable bowel syndrome (IBS) pathology.
- ***Modulation*:** Improving patient responses to already existing treatments or therapies by **modulating** the microbiome.
    - E.g., Administer a fecal microbiome transplant to improve immunotherapy efficacy in patients with cancer.
- ***Mechanism*:** Causally determining how the microbiome relates to a disease to **identify** clinically viable therapeutic targets.
    - E.g., Identify a microbial enzyme or metabolite that is deficient in people with Parkinson's disease as a novel intervention target to be developed.

Projects should seek to develop therapeutic or preventative strategies that leverage the microbiome towards improving the health of Canadians, including:

- Health Canada or FDA approved and/or investigational drugs, such as small molecules, biologics, and live biotherapeutic products.
- Dietary substrates, including, but not limited to, prebiotics, fibres, or oligosaccharides.

- Microbial-derived products, such as fecal microbiome transplants (FMT) and probiotics.

Projects should identify and develop a scalable, microbiome-based intervention with a clear hypothesis for their underlying mechanisms of action to improve health outcomes in Canadians. These interventions should have potential to expand on these findings in large clinical intervention studies. Therefore, the following examples are **not eligible**:

- Dietary interventions where the gut microbiome is assessed as an exploratory outcome
- Testing existing probiotics/prebiotics available in the Canadian market in a new health condition without a strong rationale or mechanistic target for why the probiotic/prebiotic could improve the health condition

Projects must develop or build on therapies that influence the microbiome to improve health outcomes in targeted patient cohorts and/or the general population.

Applicants are encouraged to consult with the Foundation should they have any questions regarding the eligibility of their proposed project. Please note that the Foundation prioritizes projects that involve human participants or human-derived samples (e.g., organoids, which are available through the Canadian National Organoid Network, as per below) where possible.

Ideal research seeks to do proof-of-principle work that aims to upscale the research and make it amenable to future real-world impact. Proof-of-Principle projects with a measurable track record of success and the potential to upscale (ex., human trials, drug development) may be eligible for additional funding by the Weston Family Foundation for follow-up work.

Please see Section 10 for definitions of key terms.

Section 2: Funding Specifications

The Foundation is committing up to **$3.6M in total funding** to projects selected through this program (approximately ~ 13 projects). All funding is in Canadian dollars (CAD). Funding is contingent on the receipt of a sufficient number of high-quality applications. The Foundation reserves the right to modify the total funding envelope.

Project Funding

- Grants will provide up to $300,000 per project for clinical projects that involve active patient engagement and testing and up to $200,000 for projects not working with patients.

- Funds will be used over up to 30 months.
- Funds will be granted only for direct costs that are appropriate and justifiable for the work proposed.
- Items and cost must be clearly described in the budget of the full Proposal.
- Funds cannot be used for large equipment purchases, computer purchases, administrative costs, institutional overhead or any indirect costs, unless written approval from the Foundation is received.
- **Funds cannot be used for administrative or indirect costs or for salaries for people who already receive salaries from their institutions.**
- The granted funds may deviate from the full amount requested.
- Travel expenses to scientific conferences/meetings to present work funded by the Foundation can be included in the budget.
- Each item and its cost must be clearly described in the budget (provided at the Proposal stage).
- Budgets should be developed to account for rising costs during the tenure of the project.
- **The amount granted may not be for the full amount requested if the review committee only recommends part of the project for funding.**
- **A proportion of the funds can be used for unique international resources (e.g., in licensing IP, costs associated with accessing a database). However, it is expected that the majority of the funds will go towards work conducted in Canada.**

Any grant provided by the Foundation pursuant to this Program shall be directed to the 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 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 Requests for Applications (RFAs).

Section 3: Application Process

There are two stages to this program competition: Letters of Intent (LOIs) and Proposals. **Applicants may submit a maximum of one application, when acting as a Principal Applicant, to the program.** Applicants must submit a LOI to the Foundation to be considered for Proposal submission. Each LOI will be reviewed internally by the Foundation and peer reviewed by a scientific advisory committee.

The LOI stage of the application process is a brief but significant stage of evaluation. It is expected that only a small proportion of applicants will be invited to submit full Proposals. 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 may receive written feedback from the scientific review committee at the discretion of the Foundation. No appeal process is available.

Contracting must be completed within two 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.

LOIs and Proposals must be submitted using the Foundation's online grants management system, available at westonfdn.smartsimple.ca. Applicants are invited and encouraged to contact staff at microbiome@westonfoundation.ca for any questions related to their application.

If awarded, applicants must ensure that the grant agreement is reviewed and signed within 2 weeks of notification of selection; otherwise, the Foundation reserves the right to cancel the grant.

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Information Webinar

The Foundation will host Information Webinars on **May 1st and May 6th, 2025, at 2:00 PM EST.** Details will be forwarded to interested applicants in advance of the meeting and can be found on the Foundation website. Applicants are asked to indicate their intention to join the meeting by emailing microbiome@westonfoundation.ca or by signing up at the event page through the Foundation website.

Section 4: 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 scalability and real-world potential of the idea, Canadian relevance, 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 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 performed work 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 grounded in the state of the field and strength of the team?

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

Preliminary data: Up to one page of preliminary data can be attached to the application to support the rationale, hypothesis, and feasibility of the study.

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Additional Criteria Considered at the Proposal Stage

Integrated Development Plan (IDP): If the project is successful, what are the next steps needed to advance the application of the discovery to real-world application? Is there a strong Canadian context for this project? What additional resources (financing, infrastructure, collaborators) will be needed? What is the timeline to delivery? Please consider both short-term and long-term steps.

Experimental Approach: Are the methodologies described in sufficient detail to present a compelling action plan for addressing the proposed hypotheses? Are methods well established and have they been demonstrated to be 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?

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? Does the team have experience in translating scientific findings? Have strategic partners been identified that will facilitate the mobilization and application of newly discovered knowledge?

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 checkpoints that will help mitigate risk? Have potential problem areas been adequately considered and addressed? What are next steps if work is unsuccessful?

Regulatory and Ethics Approval

It is highly recommended that applicants initiate the process of seeking regulatory approval (e.g., Health Canada Approval, ethics etc.) 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. The review panels will prioritize projects that proactively seek to understand and address necessary regulatory approvals (Health Canada, ethics) in advance of the launch of the project. Approval of ethics will be a critical first milestone of projects selected for funding.

The Foundation will permit a **maximum** period of two-months from the project start date for grantees to secure the required regulatory approvals. Projects facing longer approval timelines will be reconsidered and may be terminated by the Foundation.

Power Calculations

Applicants should provide appropriate power calculations to justify project scale and demonstrate statistical significance of proposed studies and prospective outcomes (as necessary). It is highly recommended that applicants include a power calculation in the LOI and Proposal phase of the application, and that recruitment should exceed the calculated number of subjects based on the calculation. If a power calculation is not possible due to a lack of previous research, the power calculation of the current gold standard option or closest related therapeutic option should be included.

Section 5: Eligibility of Applicants

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

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

Projects must align with the scope of the Program as outlined. 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.

Section 6: Expected Project Outcomes

The Foundation assesses the impact of awarded grants through the results and outcomes achieved for each project. It is important that projects aim to achieve

outcomes that can address the goals of the POP 2025 program and the overall mission of the Foundation.

The following are examples of outcomes that may be expected.

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

Section 7: 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 annually. The Foundation invites Grantees to take a proactive approach to communication throughout the Project. Progress reports must be submitted in accordance with the project schedule, as

detailed in the grant agreement. Failure to submit reports on time may result in termination of the project.

- **Clinical Project Report.** For projects involving active patient engagement, grantees will be required to provide brief quarterly updates capturing trial approvals, patient recruitment and patient retention.

- **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 immediately reported to the Foundation. The Foundation will then advise how the funding may be directed.

- **Impact Monitoring Reports.** Grantees are expected to report impacts related to the funded work, including, but not limited to, academic and media publications, patent and patent licensing, novel academic and commercial partnerships, and follow-on funding. As a number of these items may occur after the grant completes, the Foundation would expect the grantee to report on these metrics annually for up to 3 years after the grant completion.

Section 8: Confidentiality

The Foundation treats all LOIs, Proposals, research projects and associated research information (collectively, the "Confidential Information") in confidence using reasonable care in protecting such Confidential Information from disclosure to third parties who do not

participate in the grant review process and Foundation assessments. All Confidential Information will be used by the Foundation and its scientific review committee for the purposes of reviews and assessments and will be shared only in accordance with the sharing policy as set out herein. Notwithstanding the foregoing, Confidential Information shall not include any information that:

a) was generally known to the public prior to the effective date of this Program announcement;
b) becomes generally known to the public through no unlawful or unauthorized act by any recipient of Confidential Information; or
c) was independently developed by the Foundation or its scientific review committee without reference to the Confidential Information.

If the Foundation or any of its scientific review committee members 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 subjected to the Foundation's standard non-disclosure agreement for such engagements.

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 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, PDTrials.org, or other appropriate public registries.

Section 10: Foundation Definitions

Microbiome-based interventions:
Microbiome-based interventions typically refer to bacterial, dietary, fecal microbial transplant, phage, fungal, or other interventions that alter the composition and/or function of a given microbiome. Bacterial interventions include probiotics or (targeted) antibiotics

that increase or decrease the amounts of different bacterial genera, species, and/or strains within the microbial community. Dietary interventions, such as fibre or fermented foods, may alter the microbiome by providing the necessary nutrients for specific microbial communities to thrive. Fecal microbial transplants transfer stools from appropriate donors into patients with a variety of disease states, like *Clostridium difficile*, with the aim to improve disease outcomes. Phage therapy uses bacteriophages, or viruses against bacteria, to target specific bacterial pathogens in the microbiome.

Microbiome-based interventions have been used in several forms over the years to alter drug metabolism, treat disease, and improve general health outcomes. By targeting the microbiome, interventions have the potential to target specific patient subgroups, improve responses to therapy, and personalize patient treatment plans.

Examples:
Patients with type 1 diabetes frequently experience co-morbid gastroenteropathy, which presents with vomiting, nausea, abdominal pain, bloating, constipation, diarrhea, and fecal incontinence. Many of these patients also experience prolonged colonic transit time, which may result in changes in the gut microbiome to increase bacterial fermentation and gas production, potentially worsening symptoms. Further, microbiome-based interventions have shown promise as potential therapies to improve symptoms and insulin sensitivity for patients with type 1 diabetes. A Danish research team tested the safety and clinical efficacy of capsule-based oral fecal microbial transplant (FMTs) treatment in a randomized controlled trial of 20 patients with type 1 diabetes and severe symptoms of gastroenteropathy. They found that capsule-based oral FMT was safe, increased microbial diversity, and significantly improved symptoms and quality of life.

Canadian National Organoid Network (CNON):
The Weston Family Foundation is supporting the creation of the Canadian National Organoid Network, which is designed to make organoids available to the Canadian research community. Organoids provide a powerful platform to study human biology and there is enormous opportunity to leverage these new tools in the study of the microbiome, examining how human tissues interact with microbiome-derived metabolites, resident bacteria, viruses, and fungi, and understanding how these relationships impact human health and disease. To reduce the barriers of introducing organoids, the Canadian National Organoid Network will improve organoid access, standardize methods, and increase education and training opportunities for this growing technology.

Applicants interested in using organoids are encouraged to reach out to the Canadian National Organoid Network to learn about best practices/methods and start-up costs that may be required for their application. Applicants will not be expected to have a track record of conducting organoid research in the past, but strong organoid-focused applications will

utilize organoid research in a way that aligns with the rest of their methodology (e.g., *in vitro*, *in vivo*) and helps identify or develop a microbiome-based therapy.

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

Clinical trial: Research in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related biomedical or behavioural outcomes.

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

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

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

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Principal Applicant:

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

Co-Applicant(s):

- Individual(s) who, with the Principal Applicant, are responsible for the planning, direction, and execution of the project.
- Co-Applicants must be at the post-doctoral level or above and working at a CRA-qualified donee institution located in Canada.

Collaborator(s):

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

For any questions regarding the program, please direct them to microbiome@westonfoundation.ca.