1

Policy Direction – Commercial Research Funding

Rationale and Relationship to Mission, Principles and Values

Since its inception in 1948, MS Canada has funded over \$204 million of research in multiple sclerosis (MS). This has resulted in the achievement of a number of significant advancements in understanding of the disease processes associated with MS. Research funded by MS Canada largely focuses on the detailed biological mechanisms of the disease, providing fundamental knowledge of how MS develops, as well as clinical and epidemiological aspects of MS. In addition to 'discovery research', MS Canada supports early stage research for new therapies, including validation of potential drugs in animal models of MS as well as a number of early stage clinical trials.

Discussions, involving people affected by MS, donors, researchers, clinicians, other health charities, business advisors, Board directors, staff and volunteers, explored the opportunity of expanding MS Canada funding to include specific funding to accelerate the delivery of treatments to people living with MS. This would be achieved by providing funding to important, early stage, translational research conducted by biotechnology and pharmaceutical companies.

This policy formalizes MS Canada's priority to accelerate the pace of research in order to translate research findings into treatments for people with MS, especially those living with progressive MS, through new forms of partnership and collaboration.

MS Canada has many assets that it can contribute to this effort, such as financial resources, access to scientific experts and a reputation for high credibility and neutrality in the MS community.

Policy Objective

The objectives of this policy are to ensure that:

 MS Canada can fund the highest quality research, wherever it resides; in academia or industry; in Canada or globally, to expedite treatments for people affected by MS, especially those living with progressive MS.

MS Canada – Policy Manual		
Applies to:	MS Canada funded researchers, volunteers and staff at all levels of the organization	
Frequency of review:		
First approved:	September 4, 2014 by Board of Directors	
Last reviewed:	February 22, 2023	
Next scheduled review:	February 2028	

- Funding for commercial research will add to and enhance MS Canada's existing portfolio of investments in traditional and targeted research in academia.
- Research which can lead to the development of new diagnostic tools and safe and effective therapies is being driven through development to a stage where commercial investment can make treatments available to people living with MS.
- MS Canada can collaborate with other health charities in Canada and elsewhere, as needed, to take advantage of prior experience investing in commercial research.
- MS Canada may collect a return on investment (ROI) from its commercial research investments, which will be used to further support research programs that benefit people affected by MS and especially those with progressive MS.

Policy Application

This policy applies to all MS Canada funded researchers, volunteers and staff at all levels of the organization.

Authorizations

The policy was approved by the Board of Directors of the MS Society of Canada on September 4, 2014.

Policy Details

Commercial Research Funding

Any investment in commercial research will continue to be extramural. MS Canada will have no responsibility to lead, or direct the research that it funds under this policy.

Funding outside of Canada

MS Canada recognizes that commercial research aimed at developing new clinical tools and therapies is taking place in leading institutions around the world. In recognizing this and the global collaborative research landscape, commercial research funded by MS Canada will not be restricted to Canadian companies. MS

MS Canada - Policy Manual		
Applies to:	MS Canada funded researchers, volunteers and staff at all levels of the organization	
Frequency of review:		
First approved:	September 4, 2014 by Board of Directors	
Last reviewed:	February 22, 2023	
Next scheduled review:	February 2028	

2

Canada will aim to fund the highest quality commercial research without regard to geography.

Collaborations

It is anticipated that, at least initially, MS Canada will form collaborations with other health charities, investor groups and commercial research organizations in order to make investments in commercial research. MS Canada recognizes that other health charities have successfully worked with industry to accelerate the translation of research discoveries to new treatments. MS Canada will aim to leverage resources, experience and knowledge from these collaborations and avoid duplication of existing efforts in commercial research.

<u>Diligence process</u>

Any potential commercial research investment must undergo a highly disciplined scientific and business review process to ensure that standards for scientific merit, feasibility, and translational capacity are met. The review will take place by subcommittee of the Medical Advisory Committee (MAC), which will be selected by the Senior Vice President, Mission with guidance from the MAC chair. The subcommittee will include ad-hoc scientific and business experts who will carefully assess the science and business aspects of the proposed investments and provide a recommendation to the MAC for informational purposes. The sub-committee will also include a member of the MAC and a person affected by MS. The MAC will provide feedback on the recommendation, and a final decision will be made by the Board of Directors. Should MS Canada co-fund commercial research in collaboration with another organization, as mentioned above, they may choose to rely on the diligence process of the collaborating organization. In this event, selected delegates from the sub-committee, and/or the Senior Vice President, Mission, may serve as observers. Any outcomes from this process will be considered by the subcommittee before they advise the MAC for final recommendation to the Board.

All commercial research investments will be made using a legal agreement that sets out the obligations of MS Canada and the company, to ensure monitoring of the research, delivery of the goals and key milestones that trigger payments for research achievements. All agreements will be reviewed by MS Canada's legal counsel to properly advise the Board and mitigate risk.

Compliance with other MS Canada policies

In funding commercial research, MS Canada will comply with other policies governing the funding of research and be in alignment with Tri-council agency

MS Canada – Policy Manual		
Applies to:	MS Canada funded researchers, volunteers and staff at all levels of the organization	
Frequency of review:		
First approved:	September 4, 2014 by Board of Directors	
Last reviewed:	February 22, 2023	
Next scheduled review:	February 2028	

3

policies for research (link to policies here) with regard to the policies on stem cell research, use of animals in research and use of human subjects in research among other areas. For indirect costs, we will comply with the policy, Prohibition of Payment of Indirect Costs of Health Research.

Policy on indirect costs

In addition, MS Canada will conduct its work using high ethical standards and in compliance with all laws and regulations governing funding to companies.

Intellectual Property

MS Canada will ensure that intellectual property generated from its investments in commercial research is appropriately protected to encourage further investment by other investors and potential commercial partners.

Return on investment

MS Canada recognizes that its primary mission is to advance science, accelerate treatments and improve quality of life for people affected by MS. Receiving a financial return on investment is a secondary goal of MS Canada.

MS Canada may collect a reasonable financial return from its investments in commercial research. The funds collected will be used to further advance research programs that will accelerate treatment development and improve quality of life for people affected by MS.

Executive Champion

The Senior Vice President, Mission is the Executive Champion of this policy

Monitoring and Compliance

The Senior Vice President, Mission is responsible for monitoring the application and compliance of this policy.

The Senior Vice President, Mission is responsible for reporting to the President and Chief Executive Officer regarding compliance with this policy.

Related Policies, Legislation

MS Canada Research Funding Programs and Awards Policies and Procedures

MS Canada – Policy Manual		
Applies to:	MS Canada funded researchers, volunteers and staff at all levels of the organization	
Frequency of review:		
First approved:	September 4, 2014 by Board of Directors	
Last reviewed:	February 22, 2023	
Next scheduled review:	February 2028	

Prohibition of Payment of Indirect Costs of Health Research Policy Direction

<u>Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018)</u>

Policy Review

The policy is to be reviewed at least once every five years following approval:

- September 2014- Approved by the Board of Directors
- February 2023 Reviewed and approved by Executive Team

Definitions:

Translational research, for the purposes of this policy, is defined as research that moves laboratory findings or basic science discoveries toward practical application for patients. As this relates to new treatments, translational research is often described as a series of steps that de-risk potential drugs before they enter clinical trials, serving as a bridge between discovery research and commercialization.

Commercial research, for the purposes of this policy, is defined as translational research taking place in companies.

MS Canada - Policy Manual		
Applies to:	MS Canada funded researchers, volunteers and staff at all levels of the organization	
Frequency of review:		
First approved:	September 4, 2014 by Board of Directors	
Last reviewed:	February 22, 2023	
Next scheduled review:	February 2028	