



The MS Society of Canada is seeking applications from investigators who wish to solicit CROs to accelerate translation of promising progressive MS research

The MS Society of Canada is launching a research funding competition that will enable principal investigators to apply for funding to pay for specific research services offered by contract research organizations (CROs) and specialized drug discovery and development organizations, with the aim of advancing research and development of treatments for progressive MS.

Background and Purpose

CROs have emerged as valuable partners in drug development, as they possess the expertise and infrastructure to conduct scientific experiments that test, validate and de-risk early stage drug discoveries. CROs offer a range of services that reduce time and costs associated with drug discovery research. In addition, they offer a high standard of quality which diminishes the chances of error and eliminates the need for hiring and training research staff.

Canada is a leader in academic research. Every day, new findings are published, advancing our understanding of biology, health and disease. However, novel ideas that are uncovered in an academic laboratory often remain there, as there is no clear path in many academic centres to pursue further testing and there is a critical gap in knowledge and resources needed to facilitate the translation of knowledge into clinical applications.

As part of a strategy to increase investment in translational and commercial research, the MS Society is exploring ways to provide the world's top researchers with the necessary tools and resources that will advance ideas across the drug discovery pipeline. Providing critical funding to researchers to pay for highly specialized services and experiments offered by CROs serves as one way to achieve this objective. At the same time, fundamental knowledge and treatments for progressive MS remain elusive. By providing funding for CRO services, the MS Society may help to expedite the development of safe and effective treatments for this form of the disease.

Term and Funding

- Applicants can request a maximum of up to 100,000 CAD. Budget breakdown and adequate justification of expenses must be provided in the application.
- The funding term can be up to 1 year with no renewal.
- Funds will be released either as a lump sum or in installments depending on the size and scope of the research that will be conducted by the CRO. This will be reviewed and determined by the MS Society's Translational and Commercial Research Advisory Committee (TCRAC).
- For installment funding, release of subsequent funds is contingent on satisfactory completion of project milestones and deliverables, at the discretion of the MS Society's TCRAC.

Eligibility

Interested applicants must be eligible by their host institutions to apply for and hold a grant, and must hold a faculty appointment at a Canadian institution. The CRO does not have to be based in Canada.

The Principal Investigator (PI), who will be listed as the applicant and who will contract the CRO, must be conducting research in MS or a closely related field, be autonomous in their research activities, and have the necessary capacity and expertise to conduct high quality research and publish research outputs.

Services which are deemed eligible for funding are:

- Research experiments conducted by CROs which are intended to **optimize the therapeutic potential** of fundamental **progressive MS** research findings, and move them through the critical early stages of drug discovery (target validation, screening, hit to lead identification, lead optimization, candidate selection, etc.). Examples include:
 - Target validation assays
 - Library screens
 - Pharmacokinetics/pharmacodynamics studies
 - Toxicology studies
- Research experiments intended to optimize the therapeutic potential of fundamental progressive MS research findings, and which **cannot be conducted** at the host institution of the PI, or through academic collaboration, due to reasons such as:
 - It would be too difficult, time-consuming, and/or costly to perform at the host institution.

- There is a lack of infrastructure, staff and/or resources at the host institution.
- The experiment or service is highly specialized and can only be performed by the selected CRO (e.g. highly specialized animal model validation and efficacy studies).
- **Adequate justification** must be provided to demonstrate the above circumstances or if there is a particular experiment that is not included in the above list of eligible activities.

Services which are deemed ineligible for funding (unless proper justification is provided) are:

- Project management fees*
- Consulting fees*
- Research experiments that can be conducted at the host institution and do not require specialized expertise
- Clinical trials

*If some level of project management or consulting (e.g. additional data analysis) is required, the applicant must outline these services in detail and provide **adequate justification** in the application.

Application Format (*Note: applications will only be accepted in English*)

Online Application Procedure

The MS Society uses an online research grants and awards management system that enables researchers to submit, and review, applications on the Web. The system is called **Easygrants** and can be accessed through the following website: <https://www.mscanadagrants.ca>

Interested applicants must create a profile on Easygrants through which they can complete the application process. Important things to note:

- If you have already created a profile, please use the same log in and password for that profile. If you forgot your password, please contact msresearchgrants@mssociety.ca or select **Forgot Your Password?** on the home page.
- Please review eligibility and policies in the CRO fund RFA prior to submitting an application. If you have any questions, please contact msresearchgrants@mssociety.ca.
- Please ensure that your contact information (institution, primary address, phone number and e-mail) are correct and up to date. It is the applicant's responsibility to ensure that the submitted application contains all required components.
- Failure to submit all required information and documents will result in an incomplete application and disqualification from the competition.

Components of Application

1. Lay Summary

Provide a brief summary (**maximum 200 words**) of the proposed research using non-technical language that is easily understandable to the general public. Describe the importance of the work that will be done by the CRO, and how the outcomes will influence the development and translation of the research into a viable, safe, and effective treatment(s) for progressive MS. The summary will be reviewed by the Lay Member of the TCRAC, who will comment on the relevance and impact of this project on those who are affected by the disease. Please type the Lay Summary directly in the text box provided in Easygrants.

2. Scientific Proposal

Prepare a **maximum 5 page** proposal addressing the items below. You may use headings for each section. The proposal must be uploaded as a single document in the designated **Uploads** Section in Easygrants.

Format: Single spaced, font type and size must be Times New Roman 12 points; margins are ½"; Pages in excess of the 5 page limit **will not** be reviewed.

- Brief summary of current research activities.
- Description of translational potential of research; for example:
 - If the research conducted by the CRO is successful, what will the next steps be?
 - How will you apply or integrate the data that is collected from the CRO into your current research?
 - How will the data generated by the CRO shift the research from lab to clinic, and ultimately lead to meaningful outcomes for people living with progressive MS?
- Description of services and experiments to be provided and conducted by CRO and how they will enhance your current research.
- Brief description of the CRO, justification of selection and explanation of why the proposed experiments should be conducted by the chosen CRO.
- Project timelines and deliverables:
 - Describe the duration of the experiment to be conducted by the CRO.
 - If multiple experiments are involved, provide an estimated timeline of experiments and durations within the funding term.
 - The TCRAC will review the timelines to determine if funds will be released in full or in installments based on completion of deliverables.
- Intellectual Property (IP) plan: declare the IP status and ownership of the data that will arise from the experiment(s) conducted by the CRO.

3. Additional Required Documents:

Upload the following additional documents in the designated **Uploads** section in Easygrants. No word limits or page maximums are imposed.

- Budget
 - Amount requested by CRO (detailed quote(s)/estimate(s) from CRO showing breakdown of expenses is required).
 - Budget explanation and justification.
- Curriculum Vitae (CV)
 - Applicants are required to upload a CV which follows the **Common CV** format from the Canadian Institutes of Health Research (CIHR). The template for the Common CV can be found at <https://ccv-cvc.ca>
 - Please note the following steps:
 1. Please choose "MSSC" as the agency and select CRO template, click next.
 2. Save the Common CV to your Desktop and upload it in Easygrants.
 3. The CV must include publications (relevant to your project) from the past five (5) years.
 4. Enter all the relevant and necessary information and click "Done".
 5. A validation will automatically be performed and errors, if any, will be displayed.
 6. Review the CCV data online via a preview of the PDF.
 7. When complete, click on "Submit".
- Required Signatures
 - Principal Investigator
 - Head of Department
 - Dean of Faculty or Institution are required
 - Electronic signatures will be accepted
 - A template will be provided
- Appendix
 - Additional supplementary data, figures, information about the CRO, quotes, etc.

Review and Final Recommendation

All applications will be vetted by MS Society research staff for relevance and eligibility. Any applications that do not meet the eligibility requirements or are incomplete will be disqualified from the competition.

Eligible applications will be reviewed by the TCRAC based on the review criteria outlined below. The committee will score each application based on the review criteria outlined below.

Additional expertise (e.g. medicinal chemistry, regulatory, commercial, etc.) may be solicited for the review depending on the nature of the applications.

Any additional comments and questions raised by the TCRAC during the review must be addressed by the applicant before a recommendation for funding is made. The TCRAC may also provide feedback regarding the CRO that has been selected, or may wish to review the contract that has been drafted with the CRO, depending on the type of CRO selected and nature of the experiments that will be conducted by the CRO.

Following the review, a recommendation for funding will be presented to the MS Society's Medical Advisory Committee (MAC). Final approval will be issued by the MS Society's National Board of Directors.

Review Criteria

- **Research approach:**
 - Has the PI conducted sufficient preliminary research to provide the foundation for pursuing translational efforts to identify a target and/or identify and develop a compound?
- **Relevance:**
 - Is the proposed research relevant to progressive MS, and will the experiments conducted by the CRO contribute to the development of a potential treatment for progressive MS?
 - Are the proposed experiments relevant to progressive MS pathology and mechanisms?
- **Appropriateness:**
 - Has the PI identified the appropriate CRO to do the work that is required (e.g. do they have the necessary resources, personnel and expertise)?
 - Has the PI provided adequate justification for their selection of the CRO and have they explained what expertise the CRO will provide?
 - Are the experiments appropriate and justified (e.g. is toxicology the appropriate step at this stage of the research?)
 - Can this work be done by the host institution or through collaboration?
- **Investigator(s):**
 - Does the PI have the resources, skills and capacity to take the data and outcomes from the experiments conducted by the CRO and apply them towards ongoing development of progressive MS therapies?
 - Is there a clear short and/or long term translational plan?
- **Impact:**
 - Will the data and outcomes from the CRO help drive the translational and commercial progress of the PI's research?
 - Will the CRO's results open new pathways for treatment development in progressive MS?

- **Budget:**
 - Is the budget appropriate and realistic?
 - Should funding milestones (e.g. go/no-go) be implemented (if not already indicated in the proposal)?

Notification and Implementation

The successful applicant(s) will be notified by the MS Society via email. An agreement will be drafted between the MS Society and the host institution. Once the agreement is signed, the PI and their host institution will be expected to contract directly with the CRO. Funds will be issued upon MSSC approval and successful execution of the CRO contract.

Progress Tracking

Check-in calls may be scheduled between the MS Society, the PI and the CRO depending on the research being conducted, and the timelines and deliverables proposed. A financial report and scientific progress report will be required from the PI following completion of the research by the CRO.

Application Timeline

This is an open competition with no set deadline. Interested candidates can submit an application at any time unless otherwise stated. Review of applications will take place at the following scheduled TCRAC meeting.

Questions and Support

Please direct any questions regarding this funding opportunity to:

Angelica Asis

Manager, Research Information and Partnerships

MS Society of Canada

250 Dundas West, Suite 500

Toronto, ON, M5T 2Z5

416-922-6600 ext. 3194

angelica.asis@mssociety.ca

MS Society of Canada CRO Grant Policies

Obligations under Law: These Policies should be read in conjunction with all applicable laws including, without limitation, all applicable privacy and health information laws, government regulations and guidelines.

Agreement: A letter of agreement will be issued between the PI, the host institution and the MS Society of Canada (MSSC). A fully executed letter of agreement must be returned to the MSSC in order for the funds to be released.

Release of Funds: Funds will be remitted as stated in the letter of agreement and accounting procedures to the institution. The payment schedule will be determined by the MSSC based on feedback from the TCRAC during the review (e.g. payment in full or in installments). The TCRAC will take into account the size and scope of the experiments that will be undertaken by the CRO, and whether milestones need to be implemented. If milestones are established, funds will be released based on successful completion of those milestones, at the discretion of the MSSC.

Contracting with CRO: It is the responsibility of the PI and host institution to negotiate a contract with the selected CRO following execution of a signed MSSC agreement. The PI/institution is responsible for paying the CRO in accordance with the executed contract. MSSC funds will be released to the PI upon execution of a signed CRO contract that has been reviewed and approved by the TCRAC and MSSC. Scientific scope, experiment timelines and payment details outlined in the CRO contract must align with those in the approved proposal and MSSC agreement. If the PI cannot establish a contract with the CRO that is in line with the proposal and MSSC agreement, the PI can select a different CRO given that they provide adequate justification to the MSSC in the form of a letter on institutional letterhead. The MSSC reserves the right to terminate the grant if discrepancies cannot be resolved, if proper justification is not provided, or if there are significant delays.

Interruption or Delay: The PI must notify the MSSC immediately of any interruption or delays associated with the CRO services. The PI must advise the MSSC of (1) the work that has been interrupted or delayed; (2) the reason for the interruption or delay, and; (3) the date when the work will resume. Delays beyond sixty (60) days and failure to notify the MSSC will result in termination of the grant.

Change of CRO: If the PI opts to change CROs during the grant term, they are required to notify the MSSC immediately and provide adequate justification as to why they are changing CROs in the form of a letter on institutional letterhead. Changing CROs is subject to MSSC review and approval.

Cancellation or Suspension of CRO: If the PI and/or institution decides to cancel or suspend the CRO services or the CRO has terminated their services early, the MSSC must be notified immediately. The PI and institution must return unspent funds to the MSSC within three (3) months. The PI and/or institution must adhere to financial reporting. The agreement will be terminated between the PI and/or institution and MSSC. The PI and/or Institution remain obliged to pay any outstanding balance to the CRO after the termination of the grant.

Change of PI: In most cases, a grant terminates when the PI becomes unable to continue supervision of the research. However, within thirty (30) days after such an occurrence, the institution may request that the grant be continued with the responsibility transferred to a new PI until the grant can be terminated appropriately or until a new and complete application can be submitted by the new PI. Such changes cannot be effected without prior approval in writing by the MSSC.

Termination by PI/Institution: The grant may be terminated before the end of the project: (1) if the PI requests, in writing, that the grant be terminated, and; (2) if the sponsoring institution requests in writing that the grant be terminated because of the PI's termination of his/her academic appointment. The PI and/or institution must return any unspent funds. The PI and/or Institution remain obliged to pay any outstanding balance to the CRO after the termination of the grant as of the effective date.

Termination by MSSC: The grant may be terminated before the end of the project: (1) if the PI fails to notify the MSSC of any change in his/her affiliation with the department or institution on record at the time the grant was made; (2) if the PI changes any aspect of the grant from that which was originally approved by the MSSC; (3) when reports of progress are not received from the PI, (4) if the PI is found by an institutional investigation to have committed scientific misconduct or fraud; (5) the PI fails to meet the milestone/deliverables originally approved by the MSSC; or (6) by action of the Board of Directors of the MSSC. As a result of the grant being terminated, the MSSC is not obligated to pay the PI and/or institution any outstanding funds beyond the date of termination.

Allowable Expenses: Funds from the grant can only be used for eligible CRO services outlined above. Other experiments or services must be adequately justified in the proposal, and are subject to review and approval by the TCRAC and MSSC. The PI may not request or use funds for the following categories of expenditure: salaries for professional and non-professional personnel, patient costs, permanent equipment and consumable supplies, publication costs and travel. Funding is solely intended for research conducted by a CRO.

Indirect Costs: The MSSC will not fund indirect or overhead costs (defined as costs associated with institution's ongoing operating expenses such as facilities and basic utilities, the purchase

and repair of office equipment, administration fees, etc.). As a member of the Health Charities Coalition of Canada, the MSSC believes that indirect costs are the responsibility of the institutions or the governments that support those institutions.

Professional Support: The MSSC does not pay for salaries of the PIs nor the salaries of any co-investigators, collaborators and faculty members. Investigators are not considered employees of the MSSC but rather of the institution where the research is conducted. The research grant is to be administered in accordance with the prevailing policies of the host institution.

Reallocation of Funds: Unless adequate justification has been obtained from and approved by the MSSC, expenditures not specifically included in the budget of the approved grant will not be funded.

No Cost Extension: An extension of the term of a grant without additional funds may be approved when requested and justified in writing by the PI. An extension may be granted for up to 12 months and may only be requested once for any given term. A written request on institutional letterhead for an extension must include: (1) the amount of money to be carried into the extension period; (2) a statement of why the funds were not used in the original term; (3) a statement of how the funds will be used during the extension, and; (4) an official up-to-date financial report. A request for an extension must be made at least ninety (90) days before the termination date of a grant.

Unspent Funds: Any excess funds which remain after the experiments are completed by the CRO must be returned to the MSSC within three (3) months.

Availability of Funds: Notwithstanding any funding obligations under the letter of agreement, all funds are subject to the ongoing financial ability of the MSSC to meet such obligations. Upon a determination by the MSSC, in its sole discretion, that it does not have amounts readily available and designated to provide the funds under the agreement, the MSSC may elect not to advance any or all funds.

Acknowledgement: The MSSC must be acknowledged in any scientific publications, communications materials and conference proceedings that include data generated from MSSC-funded research (e.g. publications, scientific exhibits, scientific presentations, press releases, etc.). The following acknowledgment or its equivalent should be used:

“The research was supported (in part) by a grant(s) from the Multiple Sclerosis Society of Canada.”

Media and Communications: The MSSC expects that if a PI’s host Institution and/or publisher is preparing a press release or other media announcement related to an MSSC-funded grant, the

institution and/or publisher and the researcher shall contact msresearchgrants@mssociety.ca. Any media or other public-facing content that highlights research funded by the MSSC must be reviewed by the MSSC to ensure accuracy and appropriate acknowledgement. Failure to notify the MSSC of such communications may result in suspension of funds.

Knowledge Translation: To help increase stakeholder awareness of the research funded by the MSSC, the PI may expect the MSSC to call upon them during the term of the grant to summarize research related activities to a lay audience or the media. It is also expected that the PI participates in public events that help raise awareness of the MSSC's research program and impact of MSSC funded research. Failure to do so may result in suspension of funds.

Intellectual Property (IP): The MSSC does not own IP on outcomes of research that it funds. The MSSC will endeavor to ensure that IP generated from its investments in commercial research is appropriately protected to encourage further investment by other investors and potential commercial partners. Investigators contracting with a CRO must declare the IP status and ownership of data arising from experiments conducted by the CRO.

Return on Investment: The MSSC may collect a reasonable financial return from its investments in translational and commercial research, if the investment results in inventions which are later commercialized. If any inventions are made during the course of the CRO work, such inventions will be disclosed promptly to MSSC. 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.

Research Involving Human Subjects: The MSSC requires PIs who are contracting with CROs to ensure that the CRO has the appropriate ethics approvals and certifications to conduct human research, if applicable, in order to receive funding.

Research Involving Stem Cells: The MSSC believes that there is evidence of important benefits to people with MS through stem cell research. Accordingly, it will consider funding research on all types of human stem cells if that research follows Federal Government legislation and Canadian Institutes of Health Research (CIHR) guidelines and receives all other necessary approvals.

Research Involving Animals: The MSSC requires PIs, who are contracting with CROs to conduct research involving animals, ensure that the CRO has the appropriate ethics approvals and certifications to conduct such animal research, if applicable, in order to receive funding.

Indemnification Policy: The MSSC is not responsible for any claim, judgment, award, damages, settlement, negligence or malpractice arising from the research project or investigation related to this grant. The PI and Institution acknowledge responsibility for the conduct of research or

investigation related to this grant, and release of the MSSC from all claims or liability that may arise from the conduct of research or investigation related to this grant resulting from any act or omission on the part of the PI and Institution, their employees, agents or representatives to the extent allowed by applicable law.

Equal Opportunity Regulations: The MSSC adheres to a policy of equal opportunity in employment and requires that all Canadian institutions to which its research or training awards are made adhere to federally or provincially mandated equal opportunity policies. Institutions outside of Canada must adhere to locally applicable equal opportunity policies.

Availability of Resources: PIs who receive funds from the MSSC are expected to share research resources developed with the MSSC's support with other investigators when possible.

Scientific Misconduct and Fraud: Any institution that receives funds from the MSSC must have written policy guidelines on conflict of interest and scientific misconduct and fraud. It is the responsibility of the Institution and the PI to inform the MSSC immediately, in writing, of any institutional investigation into the conduct of a PI whose work is supported by the MSSC, and to keep the MSSC informed in a timely manner of the progress and outcome of such investigation. A finding by the institutional investigation that the PI was guilty of research fraud or misconduct is sufficient grounds to terminate MSSC support of a project, and may jeopardize future support for the PI from the MSSC.