



**Stem Cell
Network**

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Clinical Trials Awards - Program Guidelines

SCN will provide up to \$1,100,000 to support early-stage clinical trial projects with high translational potential.

Timeline:

- Letter of Intent submissions open on Tuesday, September 3, 2024.
- Letter of Intent submission deadline is Tuesday, September 24, 2024, at 11:59 p.m. Pacific.
- Full application submission will be opened to eligible LOI submitters on Tuesday, October 1, 2024.
- Full application submission deadline is Tuesday December 3, 2024, at 5:00 p.m. ET (2:00 p.m. PT)

The Letter of Intent (LOI) and full application must be submitted using the ProposalCentral online submission platform.

Upon successful submission of an LOI and/or full application, a confirmation message will appear on the screen within ProposalCentral and a confirmation email from pcsupport@altum.com will be sent to the applicant. Add pcsupport@altum.com to the safe senders list to ensure receipt of submission confirmation.

If a confirmation email is NOT received from ProposalCentral within 48 hours of submission it is the responsibility of the lead applicant to contact SCN and ensure that the application package has been received by SCN.

Funding is dependent on the completion of SCN's 2025-2029 contribution agreement with the Government of Canada.

About the Stem Cell Network:

The Stem Cell Network (SCN) is a Canadian not-for-profit that supports stem cell and regenerative medicine research; training the next generation of highly qualified personnel; and knowledge mobilization and transfer of stem cell and regenerative medicine research.



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From the lab to the clinic, SCN's goal is to power life-saving therapies and technologies through regenerative medicine research for the benefit of all. Created in 2001, with support from the Government of Canada, the Network has grown from a few dozen labs to more than 270 world-class research groups, supporting over 250 research projects and 30 clinical trials. Since its inception, over 25 biotech companies have been catalyzed or enhanced and more than 7,000 highly qualified personnel have been trained. In 2023, the Government of Canada announced additional funding for SCN through the Strategic Science Fund that will support SCN activities and research through to the end of the decade.

The Clinical Trial Award Program:

SCN is pleased to invite proposals under the Clinical Trial Award Program. The program will support projects that focus on novel gene, cellular or stem cell-related therapeutic approaches to tissue repair and regeneration for specific diseases.

Eligible clinical trials must be testing Canadian innovations at the Phase I or II stage, have received both Research Ethics Board (REB) and Clinical Trials Approval (CTA) from Health Canada, and are not duplicative of other research taking place globally. All clinical trials must be registered on ClinicalTrials.gov. It is expected that successful projects will show incremental benefit to the patient and provide a preliminary economic analysis of the potential cost of treatment compared to current standard of care to demonstrate the value to the Canadian health care system.

Clinical Trial Awards are for up to \$1,100,000 each for 36 months (award term is April 1, 2025 to March 31, 2028). Full applications will require a strategic plan and a budget justification that corresponds with the plan. In addition, a separate detailed budget for the requested SCN funding is required. Partnerships with companies/industry, not-for-profit organizations, foundations, charities, research institutions/hospitals/universities, and government bodies are a valuable component of project proposals. Partnerships and leveraged funding (in-kind and/or cash) will increase the application's ranking. Principal Investigator (PI) salaries and indirect costs can be listed as in-kind institutional support (PI salaries at 10% and indirect costs at 40%). In addition, applications that include



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collaborations with other Canadian-based investigators and have multidisciplinary expertise will also be ranked more highly.

Specific Criteria:

- Eligible clinical trials must be at the Phase I or II stage and have both CTA and REB approvals. Please note, trials that are in the process of obtaining CTA approval from Health Canada can be submitted to SCN for review but a CTA approval letter (No Objection Letter) from Health Canada and the institutional REB for the proposed trial must be in place and shared with SCN by February 17, 2025 to be eligible for funding.
- Clinical trials funded through this program MUST be registered at ClinicalTrials.gov. Registration at ClinicalTrials.gov can occur after award notification but must be in place at or before the onset of patient enrollment.
- Projects must be within the field of regenerative medicine and led by a Canadian academic and testing a Canadian innovation.
- Projects must have an achievable patient recruitment strategy and engage patient representatives who provide insight on trial design and rollout.
- Projects are expected to take a collaborative team-based approach. Phase II trials should include multiple sites.
- Where applicable, the manufacturing for the therapy should be ready to go and be accompanied by clear manufacturing plan and contractual agreements with the manufacturer that enable prompt trial start.
- Projects must describe the need and economic feasibility of the therapy for the health care system.
- Applications should describe risk mitigation strategies to overcome challenges that could prevent clinical trial success (e.g. patient enrollment, manufacturing, partner and receptor engagement).
- SCN will contribute a maximum of 40% for the costs of a clinical trial.
- Projects must include non-federal partnerships that provide in-kind and cash contributions.
- Please note, academic or clinical institutions should serve as the sponsor on SCN funded clinical trials. However, if a trial is sponsored by an SME, then a risk mitigation letter will be required at the point of submitting the full application.



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- Include non-federal partnerships that provide in-kind and cash contributions.

General Requirements:

- Projects must be relevant to regenerative medicine; regenerative medicine is the branch of medicine that develops methods to regrow, repair or replace damaged or diseased cells, organs or tissues. Regenerative medicine includes the generation and use of therapeutic stem cells, tissue engineering and the production of artificial organs. Research applications that are focused on cancer must be regenerative in nature and/or use stem cells for addressing the proposed problem.
- Projects should be collaborative in nature - supported by dynamic, multi-disciplinary teams that are diverse and reflective of Canadian society and of all research career stages. International collaboration is also encouraged to strengthen the research activity and potential global impact.
- Projects must demonstrate research excellence, inclusive principles, Canadian leadership and innovation.
- Projects must be in the translational space.
- Project milestones and deliverables must be realistic and reasonable based on the supporting budget.
- International collaboration is also encouraged to strengthen the research activity and potential global impact.
- Projects must include a robust Highly Qualified Personnel (HQP) training plan that integrates trainees and facilitates meaningful exposure and development across the spectrum of project disciplines.
- A knowledge mobilization plan must be submitted and describe how the research will be made accessible to knowledge users outside of academia. Please note it is expected that the [Tri-Agency Open Access Policy](#) will be followed to ensure research results are made publicly accessible. SCN strongly encourages the funded teams to publish their clinical trial protocols in open access journals.
- Projects must include a description of the best practices and measures that will be adopted to ensure robust, unbiased, and reproducible results, including any laboratory/project management, data governance, good documentation practices and how demographic variables, such as sex, gender, ethnicity or age,



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are integrated into the research. Note: All proposed research should be conducted in accordance with the [Tri-Agency Framework: Responsible Conduct of Research](#).

- All applications must include a plan that describes the project Equity, Diversity, and Inclusion (EDI) considerations for hiring/team composition, training, and scientific methodologies.
- Sex and Gender in Research Training: Applicants must have completed and obtained certificates for the three courses comprising the CIHR [Online Training Modules: Integrating Sex and Gender in Health Research](#).
- Research Security: Applications must comply with the federal government's [Policy on Sensitive Technology Research and Affiliations of Concern](#) (STRAC Policy) and the [National Security Guidelines for Research Partnerships](#) (NSGRP). Refer to [SCN's Guidance on Research Security for SCN Funding Applications](#) for details.

Eligibility Requirements:

- Investigators requesting funds from SCN must be based at a Tri-Agency eligible institution and must themselves be eligible to receive Tri-Agency funding.
- Each Project must be distinct from any other application(s) submitted to SCN to avoid 'double dipping' across SCN's research funding programs.
- An applicant is limited to act as lead investigator on only one LOI submission and project application per program.
- To receive funding, successful applicants must execute a standard SCN Agreement, and take on all of the associated rights and obligations. These obligations include the requirement to provide SCN office with project reports as requested, and recognition of SCN as a funder.

Evaluation Criteria:

Applications to this program will be evaluated on the following criteria using [SCN's two-stage peer review process](#). In addition to the regenerative medicine focus of the project, the following criteria will be evaluated:

1. Scientific Innovation and Merit
2. Project Rigour and Feasibility



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3. Quality of the Team
4. Budget
5. Knowledge Mobilization Plan
6. Highly Qualified Personnel Training Plan
7. Equity, Diversity, and Inclusion Plan
8. Clinical Impact
9. Partner Support

General information about SCN's Cycle 5 Round 1 competition:

Regenerative medicine projects that are eligible for SCN funding centre on one or more of the following topics: 1) Developing or testing therapeutic approaches that are regenerative in nature, including cell and/or gene therapies; 2) Addressing the role and function of stem cells in a tissue or disease; 3) Using stem cells as a necessary component for the generation of functional cell types; or 4) Investigating a small molecule or biologic that acts on or is dependent on endogenous stem cells for its therapeutic effect.

SCN values the individual differences, lived experiences, expertise, and knowledge of those in the community regardless of age, ancestry, culture, physical ability, gender identity, race, religion, or sexual orientation. SCN realizes that diversity of perspectives produces more impactful research relevant to all Canadians, therefore all applications must include a plan that describes the project Equity, Diversity, and Inclusion (EDI) considerations for hiring/team composition, training, and scientific methodologies.

All applications to SCN funding competitions are treated as new applications. If a project was submitted to a previous SCN funding round, it is at the applicant's discretion to address any issues raised in prior peer review feedback. Peer reviewers will not be provided access to prior peer review feedback for any previous version of an application.

Eligible applications will be reviewed through an expert scientific peer review process, comprised mainly of international reviewers. Projects will then be considered for strategic fit with SCN's mandate by the [Research Management Committee](#) (RMC), and funding decisions will be taken by the Board based on RMC recommendations. Successful applicants will provide the SCN office with project and financial reports as requested, and



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projects will be regularly monitored through SCN's continual review process. During this process, the RMC will evaluate whether appropriate progress is being made, including the timely attainment of milestones and deliverables, and will make recommendations on the continuance of funding. Projects that do not make appropriate progress may have funding withheld or terminated, while those that exceed progress expectations may be considered for additional top-up support, should funds be available. More details regarding SCN's peer and strategic review process can be found [here](#).

Submission process for the Clinical Trial Awards program:

A Letter of Intent (LOI) submission is mandatory for this program. LOIs will be used to identify peer review requirements, gauge the level of interest in SCN's programs, and ensure projects fall within SCN's regenerative medicine mandate. Eligible LOIs will be invited to submit a full application on Tuesday, October 1, 2024.

LOI and full application-related questions should be addressed to Gustavo Scola or Jon Draper (ResearchSCN@stemcellnetwork.ca).