

## The Accelerating Clinical Translation Program

### Guidelines

*SCN will provide up to \$400,000 to support multi-disciplinary research that is moving towards the clinic within five years; or is addressing a key research question associated with an ongoing clinical trial.*

#### About the Stem Cell Network:

Supporting and building Canada's stem cell and regenerative medicine research sector has been the *raison d'être* of the Stem Cell Network (SCN) since its inception in 2001. Its work has been supported by the Government of Canada from the beginning, and most recently with an \$18 million commitment to fund research and training through 2019-22.

SCN's mandate is to act as a catalyst for the translation of stem cell research into clinical applications, commercial products and public policy. In just over 18 years SCN has forged a national community that has transformed stem cell research and moved it to the point where regenerative medicine is changing clinical practice. SCN has supported 170 research groups nationally; invested over \$100 million for translational research, leveraging nearly \$100M in partner contributions; catalyzed 19 clinical trials and 21 biotech start-ups. In addition, SCN established the annual Till & McCulloch Meetings and has provided training for more than 3,000 individual trainees.

#### The Accelerating Clinical Translation Program:

SCN is pleased to invite full proposals under Round 2 of the Accelerating Clinical Translation Program. The program will support multi-disciplinary research projects focused on stem cell-related technologies or cell therapies expected to reach clinical trials activity within five years. This program will also support translational research activities (including Ethical Legal and Social Implications (ELSI) questions) associated with an ongoing clinical trial that will enable the trials next phase of activity. Projects principally focused on basic research are not eligible for funding.

Awards of up to \$400,000 for 18 months will be available through this program (August 1, 2020 – January 31, 2022). The application 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 foundations, institutions, health charities or industry are an important and mandatory component of the project proposals. Partnerships and leveraged

funding (in-kind and/or cash) will increase the application's ranking. All project applications will be subject to peer review and assessment by the Stem Cell Network's Research Management Committee. Successful projects will provide the SCN office with project reports as requested and will be regularly monitored by SCN's Research Management Committee to ensure appropriate progress is being made.

#### **Specific Criteria:**

- Projects can focus on pre-clinical & toxicity tests, technology development & scale up, manufacturing requirements, validation research, proof of principle experiments in small or large animal models using novel cells, compounds/drugs, or novel transplantation approaches.
- Up to 20% of the project budget can be directed towards methodological support for clinical study design and anticipated outcomes; data collection & management; data safety monitoring and oversight; preparation of regulatory documents (e.g. Pre-CTA, CTA, REB docs); pre-clinical and clinical systematic reviews; early economic analysis; protocol development. Support can also be used for conducting patient consultations and strategies to support clinical trial study design.
- Projects must clearly articulate a translational path that details the road to clinical trial activity within five years.
- Projects must include non-federal partnerships that provide in-kind and cash contributions.

#### **General Requirements:**

- Projects must be relevant to stem cells and regenerative medicine.
- Projects must demonstrate research excellence, Canadian leadership and innovation.
- Research applications that are focused on cancer must be regenerative in nature and/or use stem cells for addressing the proposed problem.
- Projects must be in the translational space through to early stage clinical trials.
- Projects should integrate sex and gender considerations into the research, when appropriate.
- Project milestones and deliverables must be realistic and reasonable based on the supporting budget.
- 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.

- Where appropriate teams should include an ELSI (Ethical, Legal and Social Implications) expert who can address translational issues specific to the research (patient engagement, health economics, regulatory issues etc.)
- A trainee education plan must be submitted with funding applications.
- A knowledge mobilization plan must be submitted with funding applications, and adhere to the [Tri-Council Open Access Policy](#) to ensure research results are made publicly accessible.
- A plan for data management must be described. The [Draft Tri-Agency Research Data Management Policy](#) should be used as a guide for developing this plan.
- Each Project must be distinct from any other application(s) submitted to SCN to avoid 'double dipping' across SCN's research funding programs.
- Investigators requesting funds from SCN must be based at a Tri-Council eligible institution and must themselves be eligible to receive Tri-Council funding.

The full application package for the Accelerating Clinical Translation Research Program consists of:

1. The application form (document 1)
2. Investigator CVs (document 2)
3. Letters of support (document 3)
4. Project budget for requested SCN funds (document 4)
5. Supporting documents such as an approved Animal Utilization Protocol, Stem Cell Oversight Committee (SCOC) approvals for the use of human cells and tissues, approval to use biohazard agents and provisional patent filing should be submitted if applicable (document 5)
6. Institution and investigator signatures form (document 6)

The deadline to submit the full application package to [info@stemcellnetwork.ca](mailto:info@stemcellnetwork.ca) is **Wednesday, April 1, 2020 at 11:59 PM Pacific Time.**

A confirmation email will be sent within 48 hours of SCN receiving the submitted application package. If a confirmation email is **NOT** received from SCN 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.