**Advancing Clinical Trials Program**

**Application Form**

Please review the Advancing Clinical Trials Program Guidelines prior to completing this application form.

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| --- |
| The deadline to submit the full application package to info@stemcellnetwork.ca is **Thursday, August 8, 2019 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. |

**The complete application package should include the following documents:**

**The Application Form (document 1)**

Must be submitted as a single Word document that includes completed Sections 1 to 14 in single-spaced, Calibri size 12 font, with 1-inch margins. Please enter the Project Leader’s name in the headings of the document and in the title of the file (i.e. Joe Smith.docx). You may delete the specific section instructions but do not delete section headings. Please submit this document as a Word document (do not format into a PDF).

**Investigator CVs (document 2)**

Must be submitted as a single PDF file including a full Canadian Common CV in the CIHR format (Academic CV Type) <http://www.cihr-irsc.gc.ca/e/45641.html> for each investigator requesting funding from SCN. Do not submit CVs and publications for collaborators or trainees. Do not submit your CV online to CIHR, instead view it (through print function) and save as a PDF file. See section 2 of the application form for details.

**Letters of Support (document 3)**

Must be submitted as a single PDF file that includes eligible partners’ letters of support for the 25-month funding period (January 1, 2020 to January 31, 2022). See Section 8 of the application form for details.

**Project Budget for SCN Funds (document 4)**

Please use the SCN Excel budget template file to provide a detailed budget for the funding requested from SCN. This current competition is based on a 25-month funding period (January 1, 2020 to January 31, 2022). Budget expenditures should follow [Tri-Agency guidelines](http://www.nserc-crsng.gc.ca/Professors-Professeurs/FinancialAdminGuide-GuideAdminFinancier/index_eng.asp). Budget justifications should be included in Section 11 of the application form. See Section 11 of the application form for more details.

**Supporting Documents (document 5)**

Please attach Research Ethics Board Approval (REB) for all sites\*, and contract agreements between the principal site and other participating sites (in the case of a multi-centre study) as separate PDF documents. If available, please attach the Health Canada Clinical Trials Approval (CTA) letter. For applications with a pending CTA please attach a letter describing the CTA timeline (submission date, and your predicted response date from Health Canada). Applications that fail to obtain and share a Health Canada CTA approval letter for the proposed trial with SCN by November 14, 2019 will NOT be eligible for funding.

\*REB approval should have been obtained for the principal site that holds the clinical protocol; REB approvals from other sites can be forwarded to SCN once received.

**Institution and Investigator Signatures Form (document 6)**

Signatures are required from any investigator directly requesting funds from SCN for this project, and their sponsoring research institute. Please submit a single PDF file with investigator and institutional signatures, and use the form supplied by SCN. Once both parties sign the document, it may be scanned as a PDF and submitted electronically along with the rest of the application.

Please adhere to word/page counts where stated, content that exceeds these counts will not be reviewed. The maximum size of each email submission of documents **should not exceed 8MB**. If an email submission exceeds 8MB, please submit as two emails labeled Part I and Part 2. If Document 1 (Word application form) exceeds 8MB, please contact Rebecca Cadwalader (rcadwalader@stemcellnetwork.ca) to discuss file transfer.

**Please direct questions about the application process or criteria** to Jon Draper (jdraper@stemcellnetwork.ca )

### **Application Form (document 1)**

### **Section 1: Project Overview**

Project Title (max. 15 words)

Plain Language Project Title (max. 15 words)

For successful proposals, this title may be used in press releases/website content.

Project Leader and Institution

Identify *one* investigator who will be responsible for managing the project (allocation of project budgets and progress reporting to SCN). Co-leaders are not accepted. Also indicate the host institution.

Project Keywords

Please provide up to 7 keywords that identify the research focus of the project

Clinical Impact Statement

In no more than two sentences, highlight the anticipated impact of this clinical trial focusing particularly on what is novel, and will potentially benefit patients.

Milestones

Identify the milestones (timepoints that delineate key phases in a project schedule) of your trial within the 25-month funding period (January 1, 2020 to January 31, 2022).

Use bullets and one or two sentences for each milestone. Please insert additional bullets if needed.

* #1
* #2
* #3

Project Deliverables

Identify a minimum of three key project deliverables (**final outputs**) for the proposed project to be achieved within the funding term (January 1, 2020 to January 31, 2022), and list any additional key deliverables that will be achieved after the funding period.

Use bullets and one or two sentences for each deliverable. Please insert additional bullets if needed.

* #1
* #2
* #3

Long-term Translational Plan (max. 1 page)

Provide a clear description of the long-term clinical translational and strategic plan for the proposed research over the next five years (January 1, 2020 to January 31, 2025). Include details on how this trial will further the longer-term project objectives.

Executive Summary (max. 350 words)

Provide a lay summary of the proposal that highlights research excellence, Canadian leadership and innovation, project objectives and deliverables. In addition, please describe how the goals of the clinical trial will be of value to Canada and Canadians in the long-term, including any economic or social benefits that may result. Please describe the project team and other partners who are essential to delivering on the research. Please note, this summary may be used for background in press releases/website content.

**Section 2: Project Team**

**Investigator CVs (document 2)**

Team Members - In the tables below, list all proposed investigators and project collaborators. Investigators are those requesting SCN funding, while project collaborators are those who are not requesting SCN funding but who will be collaborating on the project. Provide their name, position, organization affiliations and email addresses. Provide a two- or three-line description of the role of each team member in the proposed project, clearly identifying their expertise and strengths. Finally, explain how the combined expertise of the proposed team will benefit the proposed research project.

Note that researchers at participating clinical sites should be listed under Project Collaborators (not requesting funds). Funds for patient enrollment at these sites will be directed to the lead investigator.

A single PDF file of a full Canadian Common CV <http://www.cihr-irsc.gc.ca/e/45641.html> is required for each investigator requesting funding. Collaborator or trainee CVs are not required. Do not submit your CV online to CIHR, instead, view it (through print function) and save as a PDF file.

**Investigators** (Investigators requesting funds from SCN. Must be based at a Tri-Council eligible institution and must themselves be eligible to receive Tri-Council funding):

|  |  |  |
| --- | --- | --- |
| Name | Position & Institution | Phone & Email |
| 1.  |  |  |
| Role in project: |
| 2.  |  |  |
| Role in project: |
| 3.  |  |  |
| Role in project: |
| 4.  |  |  |
| Role in project: |
| 5.  |  |  |
| Role in project: |

Please insert rows as needed.

**Project Collaborators** (Canadian and international collaborators NOT requesting funds from SCN):

|  |  |  |
| --- | --- | --- |
| Name | Position & Institution | Phone & Email |
| 1.  |  |  |
| Role in project: |
| 2.  |  |  |
| Role in project: |
| 3.  |  |  |
| Role in project: |
| 4.  |  |  |
| Role in project: |
| 5.  |  |  |
| Role in project: |

Please insert rows as needed.

**Project Highly Qualified Personnel** (research assistant, undergraduate, graduate student, postdoctoral fellow and research associates)

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Position & Institution | PI (Last Name) | Phone & Email |
| 1.  |  |  |  |
| Role in project: |
| 2.  |  |  |  |
| Role in project: |
| 3.  |  |  |  |
| Role in project: |
| 4.  |  |  |  |
| Role in project: |
| 5.  |  |  |  |
| Role in project: |
| 6.  |  |  |  |
| Role in project: |

Please insert rows as needed.

**Section 3: Research Proposal**

In a maximum of fifteen pages (including tables and figures but not references\*) please provide the following:

* A description of the background, rationale, a clear hypothesis and objectives of the project;
* An outline of the proposed study design and clinical protocol, indicating eligibility criteria, interventions (experimental and control), treatment cycles, clear endpoints, study monitoring, number and role of clinical sites and relevant associated research. Describe how the study design will address the research objectives;
* A description of the nature and conclusions of the systematic review associated with this study;
* A summary of the statistical analysis plan, including study power and a justification of samples sizes, the anticipated effect sizes and variability, and the role of a statistician in the design;
* A brief description of the cell manufacturing process, if relevant;
* A description of the patient recruitment strategy, including a realistic estimate of the anticipated number of participants and recruitment timeline. Describe any safety risks to trial participants;
* Outline how patient representatives have had input into the study design and will be engaged through the rollout of the trial;
* An explanation of the integration of project members’ expertise towards achieving the goals of the project;
* A description of how the project demonstrates and builds Canadian scientific excellence, leadership and innovation;
* Details on the anticipated key milestones for the funding period and all of the final deliverables anticipated by the end of the project. Please be sure to highlight the criteria used to ascertain deliverables have been met and how they will have a clinical and/or commercial impact;
* Information on the international competitiveness of the project, clearly articulating why the approach and team are internationally competitive;
* A description of how sex and gender have been accounted for in the project design, and
* Figures and tables that support the proposal.

References (no page limit)

Providereferences that are directly relevant to the project. Please note that appendices will not be reviewed.

**Section 4: Need and Health Economics Considerations** (max. 1 page)

Please provide a description of:

* The health, clinical or product development need that this trial will address, and your proposed solution to meeting this need;
* The economic feasibility of the therapy for the Canadian health care system, including the findings of any existing health economic assessments for the proposed trial, including the potential and incremental costs and effects of the intervention;
* The scope, scale and implementation of any health economic analysis that will be undertaken during the study period, including how the expertise of the team members will facilitate a robust study;
* The current standard of care for the disease or competing solutions to the need and how they will be complemented or exceeded by the treatment proposed in this trial, and
* An evidence-based assessment of the likelihood of the therapy will be adopted as standard of care within Canada’s health system;

**Section 5: Translation and Commercialization Considerations** (max. 1 page)

Please provide a description of:

* How the outcomes of the clinical trial will be useful for informing the next phase of the trial. Indicate the likely timeframes for moving therapies or technologies through the subsequent clinical trial phases and into the clinic;
* The current status of any IP associated with this project that are critical to success;
* An assessment of any existing or competing IP that will impact commercialization, and the “freedom to operate” that is granted by the current IP held by the applicants for this therapy or product;
* The specific commercialization strategies that will be employed, including patent and intellectual property management; technology and manufacturing scale-up; and industry receptors and/or out-licensing and company creation, and
* The role of existing partners in realizing each of the project goals, as well as a realistic assessment of engagement prospects with future partners/receptors that will be required for long-term translation or commercial development.

**Section 6: Risk Mitigation Strategies** (max. 1 page)

Please provide a description of:

* The potential challenges and risks for elements that are critical to the success of the trial (e.g. patient recruitment/participation, cell manufacturing pipeline, receptor/partner engagement or clinical site participation);
* Challenges and risks for elements that could impact the next stages of clinical testing for this therapy, and
* Alternative approaches and risk mitigation strategies that will manage the impact of challenges or pitfalls and allow milestones and deliverables to be met on time.

**Section 7: Previous or Applied for Funding** (max. 1 page)

Complete this section only if: development of this project has received prior SCN funding support; the project (or elements therein) is the subject of another current SCN funding application; the project (or elements therein) is funded (in part or fully) by other funding sources.

Please provide a description of the following:

* The nature of any previous or current SCN funding applications (i.e. project title, lead PI, award type and funding amount) that have contributed to, or overlap with this project;
* A brief summary of the major findings of prior SCN funded projects, as well as the status of the milestones and deliverables (met, delayed or abandoned) at the end of the funding period. Please describe how this previous work will be built upon by this new funding support;
* For other current SCN funding applications, outline overlap with this application, and
* For projects funded from any other source that have scientific, methodological or budgetary overlap with this proposal, please describe the nature of the funding, the overlap and how SCN funded activities will be distinct.

**Section 8: Partnerships**

**Letters of Support (document 3)**

Each application must demonstrate an ability to coordinate the funding required to ensure the success of the project. Partnerships are mandatory and high-quality partnerships will result in a higher ranking for the application during review.

Provide a letter of support on the letterhead of each partner detailing the extent of their collaboration and/or their cash and/or in-kind contribution towards the particular project. **Please add a dollar value for all in-kind contributions.** Letters of support should specifically include reference to the proposed project and any conditions placed on funding. Please submit the partner letters of support in one PDF as document 3 of the application package.

This should include:

1. Actual matching funds (specifically associated with the 25-month term of this project);
2. Ongoing leveraged funding (ongoing sources of related project funding); and
3. Future potential sources of leveraged funding (possible future funding in support of the project, letters of support are not required).

Please note, it is possible that funding support from a single source may need to be split into two or more tables. In the three tables below, please list each partner, the specific nature of the contribution, and the cash and/or in-kind contributions anticipated from the partner(s) to the project. Where a researcher has a “financial interest” in a partner, the potential conflict of interest should be declared. This does not preclude the partnership in any way, but provides transparency to the review process.

1. **Actual Matching Funds** (specifically associated with the 25-month term and key objectives of the project). Eligible matching funds can be sourced from not-for-profit organizations, foundations, institutions, industry or health charities and government, but exclude federal funds (e.g. CIHR, NSERC, SSHRC, CFI, NCEs, Genome Canada, New Frontiers Research Fund). Letters of support are required.

Although Principal Investigator salaries and indirect costs are not eligible budget items, they must be listed here as in-kind institutional support (PI salaries at 10% and indirect costs at 40%).

**For all actual matching funds, indicate the period covered by the partner contribution.**

|  |  |  |
| --- | --- | --- |
| Name of Receptor/Partner | Nature of contribution (Cash and/or in-kind) | Contribution (CA$) and period covered |
| 1.  |  |  |
| Role in project:Letter of support provided: Yes/NoPotential conflict of interest: |
| 2.  |  |  |
| Role in project:Letter of support provided: Yes/NoPotential conflict of interest: |
| 3.  |  |  |
| Role in project:Letter of support provided: Yes/NoPotential conflict of interest: |
| 4.  |  |  |
| Role in project:Letter of support provided: Yes/NoPotential conflict of Interest: |
| 5.  |  |  |
| Role in project:Letter of support provided: Not required.Potential conflict of interest: |

Please insert rows as needed.

1. **Ongoing Leveraged Funding** (ongoing sources of related project funding)

Can be sourced from not-for-profit organizations, foundations, institutions, industry or health charities and government, including federal funds (e.g. CIHR, NSERC, SSHRC, CFI, NCEs, Genome Canada, New Frontiers Research Fund). Please note, for all ongoing leveraged funding, indicate the period covered by the partner contribution.

|  |  |  |
| --- | --- | --- |
| Name of Receptor/Partner | Nature of contribution (Cash and/or in-kind) | Contribution (CA$) and period covered |
| 1.  |  |  |
| Role in project:Letter of support provided: Not required.Potential conflict of interest: |
| 2.  |  |  |
| Role in project:Letter of support provided: Not required.Potential conflict of interest: |
| 3.  |  |  |
| Role in project:Letter of support provided: Not required.Potential conflict of interest: |
| 4.  |  |  |
| Role in project:Letter of support provided: Not required.Potential conflict of interest: |
| 5.  |  |  |
| Role in project:Letter of support provided: Not required.Potential conflict of interest: |

1. **Future Potential Sources of Leveraged Funding** (letters of support are not required)

Potential additional funding that may be available to support this project, including industry, venture capital investment, philanthropy, foundations, health charities or granting agencies. Letters of support are not required for these potential partnerships. Please note, for all future potential sources of leveraged funding, indicate the period covered by the partner contribution.

|  |  |  |
| --- | --- | --- |
| Name of Receptor/Partner | Nature of contribution (Cash and/or in-kind) | Contribution (CA$) and period covered |
| 1.  |  |  |
| Role in project:Letter of support provided: Not required.Potential conflict of interest: |
| 2.  |  |  |
| Role in project:Letter of support provided: Not required.Potential conflict of interest: |
| 3.  |  |  |
| Role in project:Letter of support provided: Not required.Potential conflict of interest: |
| 4.  |  |  |
| Role in project:Letter of support provided: Not required.Potential conflict of interest: |
| 5.  |  |  |
| Role in project:Letter of support provided: Not required.Potential conflict of interest: |

Please insert rows as needed.

**Section 9: High Quality Personnel (HQP) Education Plan** (max. 1 page)

Please provide a description of:

* The design and implementation of the HQP education plan for the project. Please note, the plan should provide project-associated HQP with substantive opportunities to develop skills that will improve their career prospects and capacity to work within academia or a regenerative medicine company.
* Any particularly creative and unique training elements (e.g. leadership opportunities, industry placements, certification programs, lab exchanges, workshops etc.)

**Section 10: Knowledge Mobilization Plan** (max. 1 page)

Please provide a description of:

* A realistic description and timeline of activities for knowledge synthesis, dissemination, transfer or exchange that goes beyond publications in scientific journals. Examples might include participating in education or information sessions hosted by charities and others; engaging in social media and online activities such as webinars, and/or writing for health/science blogs, or for traditional media;
* How and when trial results will be published, even if they do not match expectations, including which clinical trial reporting guidelines (e.g. CONSORT) will be followed;
* Key target audiences, stakeholders or receptors (e.g. foundations, charities, patient organizations, industry, healthcare providers or the general public) who will benefit from the project, including how and when they will be engaged;
* Metrics for assessing the impact of knowledge mobilization strategies on target audiences, stakeholders or receptors;

Note: SCN requires that it be publicly recognized in knowledge mobilization and outreach efforts as a research funder.

**Section 11: Budget**

**Project Budget for Requested SCN Funds (document 4)**

Complete the Excel budget template provided for the funding requested from SCN (document 4 of the application package). This current competition is based on a 25-month funding period (January 1, 2020 to January 31, 2022) with four payments. Please note, year two will be split over two equal payments to accommodate mid-project reviews by SCN. Please show a detailed budget outlining all expenses for the 25-month period on the template. Add justification/comments below to support the numbers provided in the budget. four

Budget expenditures should follow the Tri-Council financial guidelines. Indirect costs and Principal Investigator salaries are not eligible expenditures. Click on the link below to view the Tri-Council financial guidelines:<http://www.nserc-crsng.gc.ca/Professors-Professeurs/FinancialAdminGuide-GuideAdminFinancier/index_eng.asp>

All funded projects must hold one investigator meeting. Please include up to $10,000 in the budget for this activity.

**Justification and Comments**

Provide justification/comments to your budget below (no page limit). Identify items by noting the Excel spreadsheet row number relevant to the item.

**Section 12: Project Management**

Please explain how the lead investigator will manage the efficient and effective execution of the project by the team (max. 2 paragraphs):

Aside from the Lead Investigator, please list below the clinical study manager within the team who is available (and readily accessible) to assist with updating project management milestones.

Name:

Position:

Institution:

Email address:

Phone Number (primary):

Phone Number (secondary):

CV / Resumé:

**Section 13: Suggested Referees**

Please suggest up to three external referees from outside Canada listing name, institution and e-mail address.

**Section 14: Attachments**

**Supporting Document (document 5)**

Please attach Research Ethics Board Approval (REB) for all sites\*, and contract agreements between the principal site and other participating sites (in the case of a multi-centre study) as separate PDF documents. If available, please attach the Health Canada Clinical Trials Approval (CTA) letter. For applications with a pending CTA please attach a letter describing the CTA timeline (submission date, and your predicted response date from Health Canada). Applications that fail to obtain and share a Health Canada CTA approval letter for the proposed trial with SCN by November 14, 2019 will NOT be eligible for funding.

\*REB approval should have been obtained for the principal site that holds the clinical protocol; REB approvals from other sites can be forwarded to SCN once received.

**Institution and Investigator Signatures Form (document 6)**

Signatures are required from any investigator directly requesting funds from SCN for this project, and their sponsor research institute. Please note, this must be submitted as a single PDF file with investigator and institutional signatures, please use the form supplied by SCN. Once both parties sign the document, it may be scanned as a PDF and submitted electronically along with the rest of the application.