

## The Clinical Trial Awards Program Application Instructions for ProposalCentral

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

### Timeline:

- Full application submission will be opened to eligible LOI submitters on Friday, September 24, 2021.
- Full application submission deadline is Wednesday, December 1, 2021, at 11:59 p.m. Pacific.

**The full application must be submitted using the [ProposalCentral](#) online submission platform.**

Upon successful submission of a 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 2022-25 contribution agreement with the Government of Canada.**

Full application-related questions should be addressed to Rebecca Cadwalader ([rcadwalader@stemcellnetwork.ca](mailto:rcadwalader@stemcellnetwork.ca)) or Jon Draper ([jdraper@stemcellnetwork.ca](mailto:jdraper@stemcellnetwork.ca)).

Instructions on using ProposalCentral to complete your application can be found below.

**Please note:** all data entry fields prefaced with a red asterisk (\*) are required entry fields that must be filled for the proposal to complete the validation process in **section 15: Validate** of the application.

## **Section 1: Title Page**

### **Project Title**

Provide the title of your project in 125 characters (approximately 20 words) or fewer.

### **Plain Language Project Title**

Provide the plain language (lay) title of your project in 125 characters (approximately 20 words) or fewer. For successful proposals, this title may be used in press releases/website content.

### **Regenerative Medicine Focus**

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.

Click “Yes” to confirm that your proposed project is focused on regenerative medicine. Applications with a focus that falls outside of the field of regenerative medicine will be considered non-eligible for SCN funding.

### **Keywords Identifying the Research Focus**

Provide five to seven keywords that identify the research focus of the project. Separate each keyword by a comma (,).

## **Section 2: Download Instructions & Templates**

### **Program Guidelines & Application Instructions**

Download the Program Guidelines, Application Instructions, Partner Details Form, and ORCID iD set-up documents here.

## Section 3: Enable Other Users to Access this Application

### Access Permissions

This screen allows you to give other users access to your grant application. Electronic signatures are required for submission; therefore you must provide that individual(s) at least **Edit** access on this screen. Please review the Signature Page to confirm the signature roles required and add as appropriate on this page. Click help icon for more information.

**Auto Notify:** To enable your co-investigators, department or grants administrators to receive system notifications, add them with at least **View** access and check the box **Auto Notify**.

### Proposal Access Rights

When you give a person access to your grant application, you can give them one of three levels of permissions. These include:

- **View** (View only. Cannot change any details.)
- **Edit** (Can view and change information in the grant application. Cannot Submit or view this Access Permission screen)
- **Administrator** (Can view, edit and submit the application. Can give access rights to others.)

### Give User Proposal Access

Steps to Give Another Person Access to Your Grant Application:

1. Make sure each person is registered. To grant access to another person, that person must be registered as a "user" in the ProposalCentral system. If they are not registered, direct them to register the same way that you did. They do not need to completely fill out their Professional Profile - only the required fields of first and last name.
2. Enter the "User ID" or the "E-Mail" of the person you wish to give access to in the "User ID/E-Mail" field of the "Proposal Access User Selector" section at the bottom of the screen then click the "Find User" button. The person will now be added to the list at the top of the page of users who have access to your application. The default access permission is "View."
3. Finally, select the permissions level for the person you have just added - View, Edit, or Administrator - then click the "Save" button.

Note: This process only gives access to your application, access to your Professional Profile must be done separately from within the Professional Profile.

## **Section 4: Lead Investigator**

The person who initially creates the LOI or proposal is pre-loaded as the Lead Investigator. Contact information from the Lead Investigator's profile shown below. Note that the affiliation for the lead investigator must match the institution that will receive the project funding. Researchers at participating clinical sites should be listed as Collaborators (not requesting funds) in **section 6: Research Team**. All SCN funds for Clinical Trial Awards, including funds for patient enrollment at additional sites, will be directed to the lead investigator. To update profile, click Edit Professional Profile. To change the Lead Investigator, select from list and click button to confirm selection.

**ORCID iD:** The entry of an ORCID iD for investigators is optional but recommended. ORCID provides a persistent digital identifier (an ORCID iD) that you own and control, and that distinguishes you from every other researcher. You can connect your iD with your professional information — affiliations, grants, publications, peer review, and more. You can use your iD to share your information with other systems, ensuring you get recognition for all your contributions, saving you time and hassle, and reducing the risk of errors.

Detailed instructions for creating or connecting to your ORCID iD to your proposal are available for download (download "Orcid ID Instructions") via **section 2 – Download Instructions and Templates**.

### **Demographics and career stage questions**

Demographic and career stage information is requested to assist SCN to develop an Equity, Diversity and Inclusion policy to meet Government expectations, and to establish an updated understanding of our community's diversity.

#### **Career stage definitions:**

ECR = Early-Career Researcher (within 5 years of first independent research appointment)

MCR = Mid-Career Researcher (within 5-15 years of first independent research appointment)

SCR = Senior-Career Researcher (started first independent research position 15+ years ago)

#### **Demographics definitions:**

\*\*Indigenous; that is First Nation (North American Indian), Métis or Inuk (Inuit).

\*\*\*Person with a disability is a person who has long-term or recurring physical, mental, sensory, psychiatric or learning impairment and:

- Who considers themselves to be disadvantaged in employment by reason of that impairment, or

- Who believes that an employer or potential employer is likely to consider them to be disadvantaged in employment by reason of that impairment, and
- Includes persons whose functional limitations owing to their impairment may have been accommodated in their current job or workplace.

### Lead Investigator Affirmation.

The Lead Investigator must confirm that all project investigators listed are eligible to receive Tri-Council funding.

**Investigators** are those requesting SCN funding. Investigators who are requesting funds from SCN must be based at a Canadian Tri-Council eligible institution and must themselves be eligible to receive Tri-Council funding. ONLY the lead and co-investigators can receive SCN funds.

**Collaborators** are Canadian or international collaborators who are not requesting SCN funding but who will be collaborating on the project.

*To be eligible, investigators must meet the CIHR [definition](#) for independent researchers. Please note: all investigators must have an academic appointment that commences by the effective date of funding and extends until the final reporting date of the award.*

## Section 5: Lead Investigator Institution

### Lead Investigator Institution

Lead Investigator Institution information from the Lead Investigator's profile is auto-populated in this section.

**Important note: the affiliation for each investigator must match the institution that will receive the project funding, therefore please ensure the correct institution is noted for each team member requesting funding from SCN. For investigators with multiple affiliations, list only the institution that will receive the project funding.**

### Host Institution Contacts

Add the designated Signing Official (e.g. Institutional Director, Department Head or Associate Dean) and Financial Officer for your institution to permit them to view and/or sign-off on the proposal submission. Both the Signing Official and the Financial Officer must have created a ProposalCentral account before they can be added, and they must be signed in to ProposalCentral with their own user account in order to sign off on the proposal submission.

## Section 6: Research Team

For Clinical Trial Awards, all funds, including those for patient enrollment at participating clinical sites, are directed to the lead investigator. Note that researchers at participating clinical sites should be listed as Collaborators (not requesting funds).

All Canadian Common CVs for co-investigators should be combined with the Canadian Common CV from the lead investigator and uploaded as a single PDF in **section 14 – Research Proposal and Other Attachments**. [Information about the Canadian Common CV can be found using this link.](#)

### Team Members Details

List all proposed co-investigators, project collaborators, and Highly Qualified Personnel (HQP). Start by inputting the individual's email address and click the Add Contact icon.

- **Under 'Add Research Team Info':**
  - Select the team member's role (co-investigator or collaborator or type of HQP).
  - Input the percentage of their working time that will be spent on the project.
- **Under 'Name':** Provide the team member's name, title, institution/organization affiliation, and department. Note that the affiliation for each investigator must match the institution that will receive the project funding, therefore please ensure the correct institution is noted for each team member requesting funding from SCN.
  - Describe the team member's research expertise contribution to the project in 300 characters (approximately 50 words). This should be a short description of the research expertise the team member will contribute to the proposed project, clearly identifying their expertise and strengths.
  - Indicate the career stage of each team member (select "Not applicable" for HQP team members).
  - Answer the demographics questions for each team member.
- **Under 'Address':** Provide the team member's city, state/province, and country.
- **Under 'Phone':** Provide the team member's work phone number.

### Notes:

- Only one investigator can be designated as the lead-investigator and this person is selected in the **section 4: Lead Investigator** tab.
- **Investigators** are those requesting SCN funding. **Investigators** who are requesting funds from SCN must be based at a Canadian Tri-Council eligible institution and must themselves be eligible to receive Tri-Council funding. **ONLY the lead and co-investigators can receive SCN funds.** Note that the affiliation for each investigator must match the institution that

will receive the project funding, therefore please ensure the correct institution is noted for each team member requesting funding from SCN.

- **Collaborators** are Canadian or international collaborators who are not requesting SCN funding but who will be collaborating on the project. Key collaborators should provide letters of support describing the nature of the contribution that they will make to the project. Collaborator letters of support should be compiled into a single PDF named "Collaborator Letters of Support" and uploaded in **section 14: Research Proposal and Other Attachments** under the "Other Documents" attachment type.
- **Highly Qualified Personnel (HQP)** includes research assistant, undergraduate student, graduate student, post-doctoral fellow, technician, research associate, and clinical staff who will be working on the project. If an HQP team member has not been recruited yet, input your own email address, the PI institution, and TBC, TBC in first and last name fields.
- It is not necessary for a team member to have a ProposalCentral user account for them to be added to the Research Team.

**Career stage definitions:**

- ECR = Early-Career Researcher (within 5 years of first independent research appointment)
- MCR = Mid-Career Researcher (within 5-15 years of first independent research appointment)
- SCR = Senior-Career Researcher (started first independent research position 15+ years ago)

**Note:** SCN follows Tri-Council guidelines regarding ECR status, which currently provide a COVID-19 pandemic related [one-year extension](#) to applicants who held ECR status as of March 1, 2020, or who secured their first academic appointment after this date.

**Demographics definitions:**

\*\*Indigenous; that is First Nation (North American Indian), Métis or Inuk (Inuit).

\*\*\*Note: Person with a disability is a person who has long-term or recurring physical, mental, sensory, psychiatric or learning impairment and:

- Who considers themselves to be disadvantaged in employment by reason of that impairment, or
- Who believes that an employer or potential employer is likely to consider them to be disadvantaged in employment by reason of that impairment, and
- Includes persons whose functional limitations owing to their impairment may have been accommodated in their current job or workplace.

## Section 7: Project Information

We suggest that you complete these sections in a Word document first, then copy and paste into the relevant boxes in this section.

### Project Abstract

In no more than 2400 characters (approximately 400 words), provide a summary of the research proposal that highlights the disease or application this regenerative medicine project will tackle, the project objectives and deliverables, and how the project shows research excellence and innovation. In addition, please describe how the research has the potential to be developed and potentially translated for health, economic or social benefits.

### Lay Summary

In no more than 1500 characters (approximately 250 words), provide a lay summary that highlights the disease or application this regenerative medicine project will tackle, the project objectives and deliverables, and how the project shows Canadian research excellence and innovation. Describe how the project outputs will deliver economic, social or health benefits for Canadians. *This summary may be used for background in press releases/website content, therefore do not include any confidential information or data in the lay summary.*

### Clinical Impact Statement

In no more than two sentences (300 characters, approximately 50 words), highlight the anticipated impact of this clinical trial focusing particularly on what is novel and will potentially benefit patients.

### Strategic Plan

Provide a clear description of the long-term clinical translational and strategic plan for the proposed research over the next five years. Include details on how this trial will further the longer-term project objectives. 1,500 characters (approximately 250 words).



## Section 8: Project Aims

Identify two to five aims that outline the central objectives of the project within the 34-month funding term (April 1, 2022 to January 31, 2025). Each aim should also be referenced and fully described within the main Research Proposal document uploaded in **section 14**. When inputting the short description of the aim in **section 8**, please start with the aim number (e.g. "Aim 1: Description of aim"). Please ignore the request to input a description of the "associated milestone" in **section 8**; the milestone descriptions should be input in **Section 9: Milestones and Deliverables**, underneath each associated Aim.

## Section 9: Milestones and Deliverables

Identify at least one milestone (timepoint that delineates a key phase in a project schedule) and at least one deliverable (final outputs) per aim for the 34-month funding term (April 1, 2022 to January 31, 2025). Deliverables may include, but are not limited to, development of new models, knowledge generation, publications and other knowledge mobilization activities, technical advancements, provisional patents filed etc.

Under each Aim, use the dropdown box to select either milestone or deliverable and then add the targeted start and completion date for each milestone or deliverable (date format mm/dd/yyyy). Input a brief description (one or two sentences) for each milestone/deliverable. Click the **+** icon to add rows for each additional milestone/deliverable.

## Section 10: Research Proposal

### Research Proposal

Upload a single PDF document of your research proposal and references as the "Research Proposal and References" attachment type in **section 14: Research Proposal and Other Attachments**. A maximum of **fifteen pages** (including tables and figures) are allocated for the description of your research proposal. Please use 12-point Calibri or Times New Roman font, single spaced format. There is no page limit for references that are directly relevant to the project proposal; please append the references at the end of the 15-page research proposal PDF file.

Your research proposal should include:

- 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;
- Where applicable, a clear manufacturing plan must be provided with a letter from the manufacturer committing to meeting the clinical trial deliverables. A PDF of the letter from the manufacturer, named "Clinical study manager CV.pdf", should be uploaded in "Other Documents " attachment type in **section 14: Research Proposal and Other Attachments**
- 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;
- A description of how research data collected during the course of this project will be managed, including privacy considerations, if any. Outline how data will be released/deposited/archived at the point of publication;
- A description of how sex and gender have been accounted for in the project design, and
- Figures and tables that support the proposal.

### **Additional Project Information**

We suggest that you complete these sections in a Word document first, then copy and paste into the relevant boxes in this section.

### **Need and Health Economics Considerations**

In no more than 3000 characters (approximately 500 words), 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;

### **Translation and Commercialization Considerations**

In no more than 3000 characters (approximately 500 words), 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.

### **Risk Mitigation Strategies**

Describe how potential challenges and risks have been accounted for and the alternative strategies that will be used to mitigate them, maximum 3000 characters (approximately 500 words). Include:

- 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.

### **Highly Qualified Personnel (HQP) Education Plan**

Please provide a description of the HQP education plan, maximum 3000 characters (approximately 500 words). Include the following:

- The overall design and implementation of the HQP education plan for the project. Please note, the plan should provide project-associated HQP with substantive opportunities to attain and develop skills that will improve their career prospects and capacity to work within academia or a regenerative medicine company.
- Any creative and unique training elements such as leadership opportunities, development of transferable skills, exposure to new disciplines, industry placements, certification programs, exchanges, workshops, ambassador or mentorship programs etc.

### **Knowledge Mobilization Plan**

Please provide a description of knowledge mobilization plan, maximum 3000 characters (approximately 500 words). Include the following:

- 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: Recognition of SCN as a research funder is required in any knowledge mobilization and outreach efforts.**

### **Project Management**

Explain how the lead investigator will manage the efficient and effective execution of the project by the team. Aside from the Lead Investigator, please list the clinical study manager within the team who is available (and readily accessible) to assist with updating project management milestones. Upload a PDF of the CV/Resumé for the clinical study manager in section 14 (“Other Documents” attachment type) and name the file “Clinical study manager CV”. Ensure that a phone number is provided for the clinical study manager in **section 6 – Research Team**. 3000 characters (approximately 500 words).

### **Team Justification**

Explain how the combined expertise of the proposed team will benefit the proposed research project. Explain how an inclusive and diverse culture will be fostered and maintained within the team. 3000 characters (approximately 500 words).

### **Previous or Applied for Funding**

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

Using a maximum of 3000 characters (approximately 500 words), provide a description of:

- 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 11: Budget Period Detail

This program is based on a 34-month funding term (April 1, 2022 to January 31, 2025). Please input a detailed budget (up to a maximum of \$1,000,000) outlining all expenses for the 34-month period. Up to a maximum of \$10,000 can be claimed for project meetings-related travel.

### Notes:

- A red warning box will appear at the top of the **section 12** page if the total budget request exceeds the maximum program award value. Budget requests that exceed the program maximum award value will prevent completion of the proposal validation in **section 15**.
- Budget expenditures must 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](#).

Use the Start Date and End Date fields to enter the start and end dates for each of the three budget periods for this program. Note that the final period ends January 31, 2025 for this program:

- Period 1 start date is April 1, 2022, end date is March 31, 2023
- Period 2 start date is April 1, 2023, end date is March 31, 2024
- Period 3 start date is April 1, 2024, end date is January 31, 2025.

The “Copy Period Forward” button will copy all budget items entered in the current period into the next period.

### Budget Filters

Selecting a lead investigator or a co-investigator name using the dropdown menu will show only that investigator’s budget details. Leave the dropdown box empty to show the budget details for all (lead and co-) investigators.

### Personnel Costs Summary

Enter the name and role of Highly Qualified Personnel (HQP; e.g. technician, undergraduate, graduate student, postdoctoral fellow and research associate) who will be working on the project. If “Other” is selected in the Role dropdown menu, use the “Other Role” field to describe the individual’s role (e.g. clinical staff). Enter the requested salary for the budget period. Use the dropdown box to allocate each expense to the investigator supervising that HQP; that expense will become part of that investigator’s sub-budget.

**Note: Indirect costs and investigator salaries are not eligible for funding, and should not be included in the budget. Instead, these should be listed as institutional in-kind contributions in partner funding (enter details into the Partner Details Form available for download in **section 2: Download Instructions & Templates**).**

### Non-Personnel Costs Summary

Enter a cost and brief description for budget items in each of the listed categories. Each budget item must be allocated to an investigator, and that expense will become part of that investigator's sub-budget. Please use the [Tri-Agency Guide on Financial Administration](#) to identify eligible expenses.

**Note: Up to a maximum of \$10,000 can be claimed for project meetings-related travel, if applicable.**

## Section 12: Budget and Partner Summary

### Budget Summary

Use this summary to view all personnel and non-personnel budget expenses that have been allocated across periods, as well as the category and budget totals.

### Budget Justification

Provide justification/comments to your budget request, in approximately 1,300 words. Identify items using the same description as employed in the budget table.

**Note: no-cost extensions will not be granted past the January 31, 2025 award end date.**

### Partners Summary

Partnerships (in-kind and cash) are mandatory and highly valuable for SCN. High quality partnerships will result in a higher ranking for the application during review. Partnerships also demonstrate a potential longer-term path for the research. As such, developing partnerships is highly encouraged.

Enter the details of the partnerships that will provide support or be leveraged to facilitate the successful completion of the project objectives. This should include actual matching funds (specifically associated with the 34-month term of this project), and ongoing leveraged funding (ongoing sources of related project funding).

Use the Partners Summary text field to provide a brief overview of the partners and their contributions to this project. 1,500 characters (approximately 250 words).

Next, provide details about the contribution each partner will make by completing the Partner Details Form available for download in **section 2: Download Instructions & Templates**. Complete one form for each partner. Once complete, save the form(s) and upload as the "Partner Details Form" attachment type in **section 14: Research Proposal and Other Attachments**.

**Notes:**

- A completed Partner Details Form is a required component for all proposals.
- 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.

**Partnership letters of support**

Please provide a letter of support on the letterhead of each partner detailing the extent of their collaboration and a dollar value for their cash and/or in-kind contribution towards the project. Partner letters of support are required for actual matching support and letters of support should specifically include reference to the proposed project and any conditions placed on funding. If no letter of support is currently available, please provide an explanation in the Partner Details Form for this partner.

Compile a single PDF file containing all partner letters of support for this project and then upload as the "Partnership Letters of Support" attachment type in **section 14: Research Proposal and Other Attachments**.

**Partner Funding Definitions:**

- **Actual Matching Funds** (specifically associated with the 34-month term and key objectives of the project).  
Eligible matching funds can be sourced from companies/industry, not-for-profit organizations, foundations, charities, research institutions/hospitals/universities, and government bodies, but exclude federal funds (CIHR, NSERC, SSHRC, CFI, NCEs, Genome Canada, New Frontiers Research Fund). Letters of support are required.
- Although **investigator salaries and indirect costs** are not eligible budget items, they must be listed here as in-kind institutional support (investigator salaries at 10% and indirect costs at 40%).
- **Indirect costs** are research costs borne by the institution that are incurred during the conduct of the research activities in the lab (e.g. space, infrastructure & equipment maintenance, core facilities, support staffing costs). 40% of these in-direct costs are eligible to be listed as in-kind institutional support.
- **Ongoing Leveraged Funding** (ongoing sources of related project funding)  
Can be sourced from companies/industry, not-for-profit organizations, foundations, charities, research institutions/hospitals/universities, and government bodies, including



federal funds (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.

### Section 13: Organization Assurances

Complete the relevant organizational assurances questions for your proposal, including:

- Human subject/tissues research ethics board (REB) approval
- Animal Utilization Protocol (AUP) approval
- Biohazard usage approval
- Health Canada Clinical Trials Application (CTA) approval

Research Ethics Board (REB) approval is mandatory for Clinical Trial funding from SCN. Please attach the trial 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.

\*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.

A Health Canada Clinical Trial Application (CTA) No Objection Letter is mandatory for the Clinical Trial Awards program and should be attached if currently available. Upload the Health Canada CTA No Objection Letter in **section 14** using the “Health Canada CTA Letter” attachment type. If the CTA approval is pending, provide a description of the CTA status and the timeline (submission date, and your predicted response date from Health Canada) for receiving approval from Health Canada.

**Note: Clinical Trial Awards applications that fail to obtain and share a Health Canada CTA No Objection Letter for the proposed trial with SCN by February 21, 2022 will NOT be eligible for funding.**

Upload a single PDF in **section 14 - Research Proposal and Other Attachments** that combines the relevant approvals documents for the Lead Investigator and all co-investigators, as applicable.

### **Clinical Trial Sponsor.**

The sponsor is an individual, institution, company or organization (for example, a contract research organization) that takes the responsibility to initiate, manage or finance the clinical trial, but does not actually conduct the investigation.

Academic or clinical institutions should serve as the sponsor on SCN funded clinical trials. However, if a trial is sponsored by an SME (Small and Medium-Sized Enterprise), then a risk mitigation letter is **required** at the point of submitting the full application. All trials must conform with the [Tri-council Policy Statement: Ethical Conduct of Research Involving Humans \(TCPS2-2018\)](#) which outlines the responsibilities of researchers, sponsors and their institution's REBs

The SME sponsoring the clinical trial must provide the risk mitigation letter on the letterhead of the SME. The letter must detail approaches and outline risk mitigation strategies for the following:

- Non-completion of the trial (e.g. due to sponsor insolvency) and mitigating impacts to all patients enrolled in the trial.
- Maintaining data integrity and confidentiality.
- QC management during the conduct of the trial.
- Describe SME in-house expertise and resources to effectively fulfill the clinical trial sponsor role.

In addition, the letter should describe the strategy and timelines the SME will follow for reporting trial data.

Upload a PDF of the SME sponsor risk mitigation letter in **section 14** ("Other Documents" attachment type) and name the file "SME sponsor risk mitigation letter".

### **Section 14: Research Proposal and Other Attachments**

In this section, upload your research proposal and other documents. Required documents are Research Proposal and References, Canadian Common CVs, and Partner Details Form. The Lead and co-investigator Common Canadian CVs should be collated into a single PDF file entitled, 'Investigator CVs' and uploaded. The Partner Details Form should be completed for each partner and/or type of funding and uploaded as a single PDF. Partnership letters of support should be collated into a single PDF document entitled, 'Partnership Letters of Support' and uploaded. Other optional documents should be uploaded under 'Other documents' attachment type. Note: only PDF files are accepted for all attachments.

Acceptable attachment types are:

- Animal Utilization Protocol (AUP) approval
- Biohazard usage approval
- Health Canada CTA Letter
- Investigator Common CVs (**REQUIRED**)
- Other Documents
- Partner Details Form (**REQUIRED**)
- Partnership Letters of Support
- Human subject/tissues research ethics board (REB) approval
- Research Proposal and References (**REQUIRED**)

For the Other Documents attachment type, the only acceptable documents are:

- Collaborator letters of support, if applicable
- Provisional patent filings, if applicable
- Manufacturer letter, if applicable
- Clinical Study Manager CV/Resume
- Contract agreements, if applicable
- SME sponsor risk mitigation letter, if applicable
- Optional: A single research article authored by the team that is specifically relevant to the proposal.

Note: PDF files are the only accepted file format for all file uploads. Where there are multiple files for a specific attachment type (e.g. A lead investigator and two co-investigator Canadian Common CVs), please compile into a single PDF and upload.

### **Section 15: Validate**

Click the 'Validate' button to check for any missing REQUIRED information or files. All missing required information will be listed on the screen. All missing information must be completed before proceeding to the next step.

### **Section 16: Signature Page and Print**

**For Clinical Trial Awards all funds are directed to the lead investigator. Signatures are required only from the lead investigator and from their institution which would receive the SCN funding for this project.**

Only the lead Investigator and their institutional signing authority should sign in the fields provided in **section 16**, by typing in their full names and clicking the Sign button. The institutional signing authority must be given access to the proposal in **section 3**, and they must be signed in to ProposalCentral with their own user account in order to sign off on the proposal submission

### **Section 17: Submit**

To submit your proposal, please click the 'Submit' button. You will be unable to submit if you have not provided all the REQUIRED information. Any missing information will be listed on the screen. If your submission is successful, you will receive a confirmation message on the screen and a confirmation email from [pcsupport@altum.com](mailto:pcsupport@altum.com) will be sent to the applicant. **Please add [pcsupport@altum.com](mailto:pcsupport@altum.com) to your safe senders list to ensure receipt of your submission.**

#### **Important Notice:**

**We recommend that you verify that the status of your application has changed to "Submitted". For best results, you should logout and close all ProposalCentral browser windows. Login and select the "Proposals" tab and select "Submitted" from the Proposal Status dropdown list. Once properly submitted, your application no longer appear on your Home tab.**

**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 has been received by SCN.**