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The Clinical Trial Awards Program

Application Instructions for ProposalCentral

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

Timeline:

- 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 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.

Full application-related questions should be addressed ResearchSCN@stemcellnetwork.ca.

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

Important notes:

- 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.
- Additional resources, videos and guides for completing your application will be available via this [link](#).



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- An application completion checklist is available for download through the “Download Instructions & Templates” tab of the application form. It is recommended that applicants cross-reference this form prior to final validation and submission.

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 following resources:

- Program Guidelines
- Research Proposal Application - Template
- Partner Details Excel Form



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- Gantt Excel chart template
- Co-Investigator Sign-off Form
- Research Security Attestation Form
- Guidance on Research Security for SCN Funding Applications
- ORCID iD set-up document
- Application completion checklist

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.



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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**.

LEAD INVESTIGATOR CAREER STAGE

This information is requested to assist SCN in reporting to the Government of Canada the career stages of investigators funded by SCN awards.



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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)

LEAD INVESTIGATOR AFFIRMATION.

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

Investigators are those requesting SCN funding. Investigators who are requesting funds from SCN must be based at a Canadian Tri-Agency eligible institution and must themselves be eligible to receive Tri-Agency funding. For the Clinical Trials Award Program, **ONLY** the lead investigator 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.



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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; the lead investigator's institution is responsible for establishing subcontracts with researchers at participating clinical sites. Note that researchers at participating clinical sites should be listed as Collaborators (not requesting funds).

All Canadian Common CVs (CIHR Academic format) 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).
 - Describe the team members' role to the project in 400 characters (approximately 50 words). This should be a short description of the role the team member will carry out in the project (i.e.: Clinician, QA, QC, cell culture technician, regulatory consultant, etc.)
 - 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.



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- 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-Agency eligible institution and must themselves be eligible to receive Tri-Agency funding. **ONLY the lead investigator can receive SCN funds** for the Clinical Trial Awards. Note that the affiliation for the 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)



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- 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-Agency guidelines regarding ECR status, which currently provide a COVID-19 pandemic related [two-year extension](#) to applicants who held ECR status between March 1, 2020 and September 15th, 2022.

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-



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term project objectives and any steps to ensure that the therapy will be made available to Canadians. 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 36-month funding term (April 1, 2025 to March 31, 2028). 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.

Click the + icon to add rows for each Aim.

Section 9: Milestones and Deliverables

Identify at least one milestone (a specific progress point or event at a key stage of achieving the project aim) and at least one deliverable (a tangible output that demonstrates progress and achievement) per aim for the 36-month funding term (April 1, 2025 to March 31, 2028).

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.

A timeline of project Aims, Milestones and Deliverables in Gantt chart format must be submitted in Section 14; please use the Gantt Excel chart template available in Section 2.

Click the + icon to add rows for each additional milestone/deliverable.



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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. IMPORTANT: Please use the Research Proposal Word Doc Template file available in Section 2 and convert it to PDF before submission. Submitted Research Proposals must be in 12-point Times New Roman font, single spaced format, all margins 2.54cm. The lead investigator's name and the funding program (i.e. Clinical Trial Awards) should be included in the header margin. 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. Note: All proposed research should be conducted in accordance with the [Tri-Agency Framework: Responsible Conduct of Research](#).

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 calculation 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 outlining the manufacturing timeline and deliverables must be provided with a letter from the manufacturer committing to meeting the clinical trial deliverables and enabling a prompt trial start. A PDF of the letter from the manufacturer, named "Manufacturer Letter.pdf", with appended contractual agreements and timelines should be uploaded in "Other Documents" attachment type in **section 14: Research Proposal and Other Attachments**;



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- 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; Resources that provide guidance on patient engagement in early-stage clinical trials are available through this [link](#).
- 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
- 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;



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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.

RESEARCH RIGOR AND RISK MITIGATION STRATEGIES

Describe the measures that will be taken to ensure robust, unbiased and reproducible results.

Describe how potential challenges and risks have been accounted for and the alternative strategies that will be used to mitigate them, maximum 4500 characters (approximately 750 words). Include:

- A description of how the experimental design and methods proposed will ensure and enhance rigor;
- A description of how inclusive design principles were integrated into the project to ensure rigour and maximize impact (e.g., consideration for demographic variables including, sex, gender, ethnicity or age).
- A description of any laboratory management, project management, data governance or good documentation practices that will be used to enhance the quality and reproducibility of outputs and reduce risk.
- For data management, include a description of how research data collected during this project will be managed, including privacy considerations, if any. Outline how data will be released/deposited/archived at the point of publication. The [Tri-Agency Research Data Management Policy](#) should serve as a guide for developing a data management plan.



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- 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). Please consult the HQP Education Plan Resource available through SCN's Research Funding [webpage](#) for guidance on developing your plan.

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.



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Please consult the Knowledge Mobilization Plan Resource available through SCN's Research Funding [webpage](#) for additional guidance on developing your plan.

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).

EQUITY, DIVERSITY, AND INCLUSION (EDI) CONSIDERATIONS

The best science is inclusive science. 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, and sexual orientation. Using a maximum of 3000 characters (approximately 500 words), explain how an inclusive and diverse culture will be fostered and maintained within the team. Also provide a high-level summary of how EDI has been infused throughout the research proposal, such as hiring/team composition, EDI training, and scientific methodologies, to ensure rigour and maximize project impact.

Please consult the EDI Resource available through SCN's Research Funding [webpage](#) for guidance on integrating EDI into your proposal.

TEAM JUSTIFICATION

Using a maximum 3000 characters (approximately 500 words), explain how the expertise and skillsets of the team members will be utilized and combined to benefit the proposed research project.

CONSIDERATION OF IMPACTS ON RESEARCH PROGRAM

Using a maximum 1500 characters (approximately 250 words), describe any impacts on the research program that should be considered during the peer and strategic review process. For example, maternity/paternity leave, career interruptions or research program disruptions arising from the COVID-19 pandemic.



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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.

PATIENT ENGAGEMENT

Patient engagement is essential to ensure that research prioritizes outcomes that are most meaningful to patients, thereby enhancing their relevance and impact on healthcare. Engaging patients from the outset improves trial designs, including recruitment strategies, eligibility criteria, and protocol development, which in turn facilitates better participant enrollment and retention. Patient engagement ensures trials align with patient interests, fostering transparency and accountability in research. This approach strengthens the justification for funding and regulatory approval while also fostering innovation and elevating overall trial quality through collaborative patient insights.

Select "Yes" if your research proposal includes meaningful patient engagement mechanisms to improve outcomes.

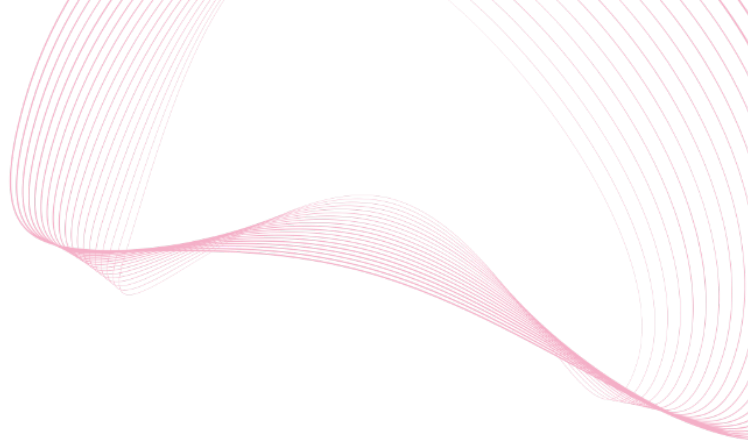


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Section 11: Budget Period Detail

This program is based on a 36-month funding term (April 1, 2025 to March 31, 2028). Please input a detailed budget (up to a maximum of \$1,100,000) outlining all expenses for the 36-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-Agency financial guidelines. Indirect Costs and Principal Investigator salaries are not eligible expenditures. Click on the link below to view the [Tri-Agency 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 March 31, 2028 for this program:

- Period 1 start date is April 1, 2025, end date is March 31, 2026
- Period 2 start date is April 1, 2026, end date is March 31, 2027
- Period 3 start date is April 1, 2027, end date is March 31, 2028

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

BUDGET FILTERS

Selecting one of the investigators names using the dropdown menu will show only that investigator’s budget details. Alternatively, leave the dropdown box empty to show the budget details for the Lead Investigator.

JOINT-FUNDER

Use this function **only if you are applying for a Joint-Funding Award**. Applicants to SCN’s standard awards should not use the Joint-Funder function, and should ignore the “Joint-funding” column for each budget category table.



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The total budget requested for a Joint-Funded Award must be allocated equally between SCN and the relevant joint-funding organization. Use the “Add funder” option to add SCN and the joint funding organization (Azrieli Foundation for Neurodevelopmental disorders or Breakthrough T1D for type 1 diabetes) as funding providers. Use the “Joint-Funding” Award drop-down column in each budget category table to select the funder to allocate the cost to. The maximum award for a joint-funded Clinical Trial Award is \$1,320,000 over 36 months; ensure that the maximum total contribution per funder is no greater than \$660,000 (half of the maximum award size). For example, if an application requested \$950,000 in total, \$475,000 of total costs should be allocated to SCN and \$475,000 should be allocated to the joint-funding organization. **Applicants should confirm that budget allocations adhere to the regulations as found in the Joint-Funded Award Guidelines document for the relevant joint-partner.**

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 Excel 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.

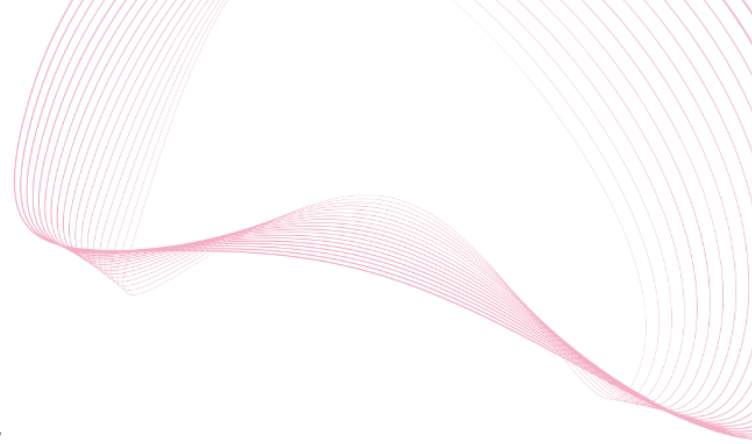


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Section 12: Budget and Partner Summary

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 10,000 characters. Identify items using the same description as employed in the budget table.

Note: no-cost extensions will not be granted past the March 31, 2028 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. **Note:** for applications to the Joint-Funding Awards, do NOT include the Joint-Funding organization contribution in this section, instead complete the Partner Details Excel Form that lists all actual matching and ongoing leverage funds/partners; a template form is available for download in [section 2](#).

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 36-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 Excel 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 Excel Form" attachment type in [section 14: Research Proposal and Other Attachments](#).



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Notes:

- A completed Partner Details Excel 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 Excel 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 36-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%). Salaries and in-direct costs from a single institution can be reported in aggregate to avoid disclosure of salary amounts.
- **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)



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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 & Required Training

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

ORGANIZATIONAL 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 and REB approval(s) for the proposed trial with SCN by **February 17, 2025** will NOT 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.

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-Agency Policy Statement: Ethical Conduct of Research Involving Humans \(TCPS2-2018\)](#) which outlines the responsibilities of researchers, sponsors and their institution's REB

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.



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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”.

REQUIRED TRAINING:

Research Security

Researchers applying to SCN for funding must be aware of the Government of Canada’s recommendations and guidelines for research security, data management, and privacy. In addition, investigators should be aware of their Institutional policies and practices as it relates to research security and research partnerships.

Guidance by the Government of Canada, along with information and tools on assessment and mitigation of risks to research, development, and intellectual property is available from the Government of Canada [National Security Guidelines for Research Partnerships](#). The [Safeguarding your Research Portal](#) is designed as a ‘how to’ for researchers to safeguard their data from foreign interference, espionage, and unwanted knowledge transfer. This includes [Mitigating economic and/or geopolitical risks in sensitive research projects](#) and [Travel security guide for university researchers and staff](#).

All applications for SCN funding must comply with the federal government’s [Policy on Sensitive Technology Research and Affiliations of Concern](#) (STRAC) and the [National Security Guidelines for Research Partnerships](#) (NSGRP).

In alignment with the STRAC Policy, funding applications submitted to SCN involving research that aims to advance a [Sensitive Technology Research Area](#) (STRA; Regenerative medicine research (including stem cells, tissue engineering or gene therapy) is considered a STRA) will not be funded if any of the researchers involved in activities supported by the award are currently affiliated with, or in receipt of funding or in-kind support, from a Named Research Organization (NRO).

The [National Security Guidelines for Research Partnerships](#) apply for research that is considered dual-use or sensitive (see the [STRA](#) list), including regenerative medicine, and involves private sector partner organizations (i.e., organizations that are not owned or operated by any order of government and includes all for-profit organizations). **Applications that include private sector partners must submit a risk assessment form.**



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Please refer to SCN's [Guidance on Research Security for SCN Funding Applications](#) available through Section 2 - Download Instructions and Templates for more information about SCN's research security process and the responsibilities of researchers.

Note: All researchers receiving SCN funds (lead and co-investigators) will need to have complete the following training courses and obtain certificates prior to the release of SCN funds: [Introduction to Research Security](#), [Dual-Use in Life Science Research](#) and [Insider and Outsider Threats](#). Submission of these certificates is not required during the application phase, but will be requested from successful applicants.

Resources:

[Policy on Sensitive Technology Research and Affiliations of Concern \(STRAC\)](#)

[National Security Guidelines for Research Partnerships \(NSGRP\)](#)

[Sensitive Technology Research Area](#)

[Named Research Organization](#)

[Introduction to Research Security](#)

[Dual-Use in Life Science Research](#)

[Insider and Outsider Threats](#)

Applicants must have:

1. All researchers (lead-investigators, co-investigators, collaborators and HQP) been made aware of the STRAC Policy, the NRO list and SCN's document "Guidance on Research Security for SCN Funding Application";
2. Be familiar with the [Safeguarding Your Research](#) Portal and completed the following training courses and obtained certificates: [Introduction to Research Security](#), [Dual-Use in Life Science Research](#) and [Insider and Outsider Threats](#). ; AND
3. Attached a single PDF that includes the completed attestation forms for all researchers with named roles (lead-investigators, co-investigators, collaborators) involved in activities supported by the project. HQP do not need to complete an attestation form.
4. For applications that include partnering with an organization from the private sector, the lead investigator must complete and upload a risk assessment form with their application that covers the proposed private sector partners for the project



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Note: Data Management guidelines from The Chief Science Advisor of Canada's Roadmap for [Open Science provides](#) principles and recommendations with respect to privacy, security, ethical considerations and intellectual property protection. Further guidelines and best practices are outlined in the [Tri-Agency Research Data Management Policy](#) and FAIR principles.

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

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](#). If any research has previously completed these courses in the last year, those completion certificates may be uploaded.

Private Sector Partnerships and Intellectual Property:

Applicants who are partnering with a private sector partner must state whether any IP related to this project will be shared, co-developed or transferred to the private sector partner.

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 (CIHR Academic format), Partner Details Excel Form, Research Security Attestations, and Gantt Excel chart timeline. The Lead and co-investigator Common Canadian CVs should be collated into a single PDF file entitled, 'Investigator CVs' and uploaded. The Partner Details Excel Form should include an entry for each Actual Matching or Ongoing Leveraged partner (do NOT include the Joint-Funding organization contribution in this form). 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 except the Partner Details Excel Form.



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Acceptable attachment types are:

- Research Proposal and References (**REQUIRED**)
- Investigator Common CVs (CIHR Academic format; **REQUIRED**)
- Research Security Attestations (**REQUIRED**)
- Gantt Excel Chart Timeline (**REQUIRED**)
- Certificate of completion of CIHR Online Training Modules: Integrating Sex and Gender in Health Research (**REQUIRED**)
- Partner Details Excel Form (**REQUIRED – upload in .XLSX format**)
- Private Sector Partner Risk Assessment Form (**if applicable**)
- Health Canada CTA No Objection Letter*
- Human subject/tissues research ethics board (REB) approval*
- Animal Utilization Protocol (AUP) approval
- Biohazard usage approval
- Partnership Letters of Support
- Other Documents

*A Health Canada CTA No Objection Letter and REB approval(s) for the proposed trial must be shared with SCN by **February 17, 2025**.

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

- Clinical Study Manager CV/Resume
- Collaborator letters of support, if applicable
- Provisional patent filings, if applicable
- Manufacturer letter, if applicable
- 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.

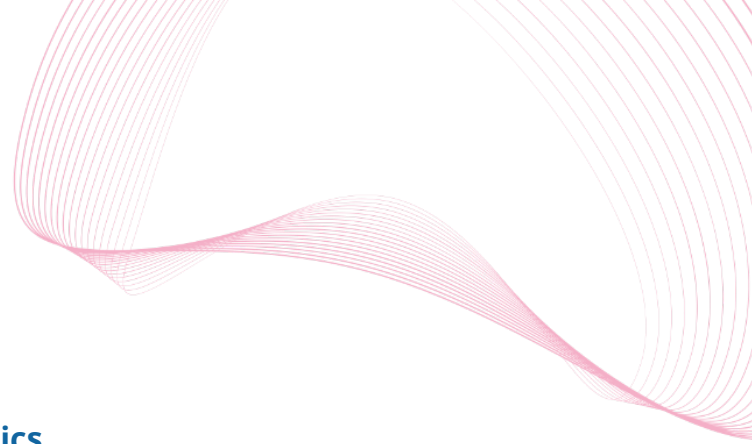


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Section 15: Lead Investigator Demographics

The best science is inclusive science, and SCN is committed to cultivating and preserving a culture of inclusion, diversity, equity and accessibility. We value the individual differences, lived experiences, expertise and knowledge of those in our community. We welcome the unique contributions of partners, employees and community members regardless of age, ancestry, culture, gender identity, physical ability, race, religion and sexual orientation.

Complete the demographics question for the Lead Investigator in this section. Self-identification information is collected as part of the application process and used for SCN's reporting purposes with the Government of Canada. All data reported to the Government of Canada is de-identified, aggregate data. The inclusion of preferred pronouns is optional; however, it helps SCN staff in their communication and correspondence with applicants.

Note: Information provided in this section is NOT available to reviewers.

Section 16: 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 17: 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 respective institutional signing authority should sign in the fields provided in [section 17](#), 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.



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All co-investigators and their respective institutional signing authorities must sign the Co-Investigator Sign-off Form, downloadable from [Section 3: Download Instructions & Templates](#). Save the completed and signed form as a PDF named 'Co-investigator Signatures' and upload it in [Section 14: Research Proposal and Other Attachments](#).

Section 18: 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 will be sent to the applicant. **Please add 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 appears 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.



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