CIHR Pan-Canadian Network for HIV and STBBI Clinical Trials Research | Réseau pancanadien pour des essais cliniques sur le VIH et autres ITSS

Seed Funding Submission and Review Process Guidance Document

After you have read this document, if you have questions, please contact:

- The CTN+ by email to submissions@hivnet.ubc.ca or echerban@hivnet.ubc.ca

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A. Introduction & Objective

Building on the success of the Pilot Study Funding Program that was implemented in previous CTN grants, the new regional Seed Funding competition will provide funds and in-kind research services to support the conduct of capacity building pilot, proof-of-concept, or feasibility studies. Regions are provided with up to $50,000 annually for this competition and in-kind research services support will be available for applicants. Each CTN+ region determines their regional priorities and is allocated $50,000 of funds from the CTN+ grant to support either one or two regional-focused studies. Regions that supplement the program with additional funds may proceed with funding additional studies. The award is intended to pay for all of the direct costs associated with the study. This Program is targeted to support new projects, thus applications from existing projects seeking top-up funding are not accepted.

This program focuses on supporting Early Career CTN+ Researchers and Postdoctoral Fellows of CTN+ Researchers. Successful applicants will gain experience on how to manage a study and how to implement a research project by collaborating with senior investigators and with the staff that provide clinical research support services. The Program is only open to CTN+ Researchers who are within ten years of their first position as an independent researcher, or if supervising a postdoctoral fellow, the Researcher must have the ability to hold funds and supervise fellows within their academic institution. Current CTN+ Postdoctoral Fellowship Awards program awardees are eligible to apply.

The competition will occur once per year and deadlines for the competition will be published on the CTN+ website calendar at: https://www.ctnplus.ca/calendar/. Note that CTN+ Researchers who are not eligible for this particular Program, but who have previously obtained a CTN+ Letter of Support and full funding from a competition external to the CTN+ (for example, a CIHR Project Grant) for a pilot or proof-of-concept study may apply to the CTN+ Portfolio competition. For details about the CTN+ Portfolio Competition, please refer to https://www.ctnplus.ca/toolbox-resources/#review for competition guidelines and use the calendar link above to identify competition deadlines.

B Competition Overview

Eligibility

The following may apply for this competition:

- CTN+ Researchers within the first 10 years of their ability to independently hold grant funds. If the applicant has taken one or more leaves of absence (for example, maternity or parental leave) they will need to provide information about the duration of each leave.
- Postdoctoral Fellows of CTN+ Researchers who are enrolled with an academic institution. CTN+ Postdoctoral Fellows are eligible to apply.
- Applicants may only apply within one region, the region that they are formally affiliated with.
- Each applicant may only submit one concept for review.

The following may not apply for this competition:

- CTN+ Researchers who have held their research position for greater than 10 years.
- Postdoctoral fellows whose supervisor is not a CTN+ Researcher.

- CTN+ Researchers or their postdoctoral fellows can only apply within the region with which they are affiliated, cross-region applicants will not be accepted.

This competition occurs in two stages.
NOTE: to assist applicants with preparing their concept form and full submission, the required contents for both stages are in Appendix B.

1. Regional Triage
- Eligible applicants must complete a Seed Fund concept form online at: https://apply.med.ubc.ca/prog/ctn_seed_funding_competition/
- Regions will determine the number of studies the competition will support within their region.
- Applicants may only submit in one region, the region in which their institutional affiliation is based. In addition, each individual applicant may only submit one concept.
- Concepts must align to both the CTN+ scientific priorities (see: https://www.ctnplus.ca/priorities) and regional priorities (see: https://www.ctnplus.ca/about/).
- No outside funds may be used. For example, applicants may not submit study concepts for which they currently have funding and additional funding from other competitions should not be requested. Applicants may use in-kind services from their institution, for example, statistical analysis or investigational study drug already held at their institution.
- Supported by the CTN+ staff, regional leadership teams will meet to review and rank the concepts. The concepts will be ranked upon their applicability to the CTN+ scientific and regional priorities, scientific merit (including the ability to use the data from the Seed competition to design a larger study for a grant application), feasibility, ability to proceed with the study within 12 months of approval, and regional capacity-building impact.
- CTN+ staff will invite the top-ranked applicants to complete a full submission online by providing the link for submission.

2. CTN+ Review
- The CTN+ has three review cycles and this competition will always be reviewed within the first review cycle (Cycle 1) within any given calendar year.
- Via the CTN+ review process, non-conflicted, scientific, community, methodological, and if relevant, Indigenous experts will be assigned for each full submission. If reviewers have questions, CTN+ may contact applicants for clarification prior to the review process completion.
- Successful applicants will be provided with their review score and, if applicable, reviewer comments, in addition to details about the amount of funds and in-kind services that are provided for their study.

The following types of studies are <u>not eligible</u>:

- Basic science or lab-based studies that do not include any clinical research in humans;
- Studies with a source of funds previously attained or with a plan to submit another grant for additional funding;
- Development of a clinical tool or algorithm;
- Health economic analysis of projects not approved by the CTN+;
- Epidemiological observation of a population with one time point;

- Disease surveillance; and
- Clinical guidelines

CTN+ In-Kind Clinical Research Services

Proportionate to the value and requirements of the study (for example, a feasibility study approved for $25,000 will not be provided with more than $50,000 of in-kind services), applicants may request in-kind clinical research services to support their study. If services are approved, CTN+ staff will assist the applicant in sourcing the relevant services with Network. Note, services may or may not be provided within their home region. The list of services can be found at https://www.ctnplus.ca/services and for this competition, cost-recovery services will be provided in-kind.

Post-Approval Process

Within six weeks of the review process, the applicant will receive an award letter from the National Director that outlines the review results and describes the resource allocation. Successful applicants may be required to respond to the reviewers in writing before final approval is provided.

Investigators of CTN+ approved projects are required to provide the CTN+ with reports, quarterly enrolment updates, documents, and are required to acknowledge CTN+ support when issuing publications, scientific presentations, press releases, and other documents describing projects or programs supported by the CTN+ in whole or in part. The CTN+ Publication Guidelines are available at https://www.ctnplus.ca/publicationguidelines.

Investigators who suspend CTN+ approved projects, for any reason, are required to report this suspension to the CTN+ immediately.

To undertake their project, successful applicants are required to complete the necessary requirements for their home institution, these include:

- Fulfilling their institutional Research Ethics Board requirements
- Participating, as required, in the progress of contract negotiation between their home institution and the CTN+ National Director's institution and responding to their home institution in a prompt manner to ensure that contract negotiations occur in a timely fashion
- Establishing a grant account per the requirements of their home institution, oversee (if applicable) spending for the study, and provide the CTN+ National Director's institution with financial statements as required

Appendix A: Glossary of Terms

Email submissions@hivnet.ubc.ca if you have questions or require clarification.

CTN+ Think Tanks (see: About the CTN+)
The CTN+ has four scientific Think Tanks. This structure was designed to support our researchers and community members — emerging and experienced — to generate new concepts and protocols. The Think Tanks structure is equipped to provide a forum for dynamic discussion of research ideas and the rapid movement of research initiatives into clinical trials and studies.

The four Think Tanks are:

1) Treatment & Management
2) Prevention & Testing
3) Cure & Immunotherapies
4) Methodology

Each Think Tank is led by two scientific Co-leads, an early career co-lead, a community co-lead, and is supported by a Research Associate.

CTN+ Regional Teams (see: Regional Teams)
The CTN+ prioritizes the growth of regional research capacity by fostering, developing, and supporting research teams across Canada. These regional teams, which include researchers, community members, and Indigenous representation, champion the knowledge needs of those in their local communities, with a focus on capacity building, engagement, upholding Indigenous rights, and recognizing the power of research and knowledge mobilization to improve health equity across the country.

The expertise of the Regional Team informs the Network's research priorities, special initiatives, and knowledge translation efforts. The current Regional Teams are:

1) Atlantic
2) Quebec
3) Ontario
4) Prairies
5) BC/Yukon

CTN+ Researchers
Only CTN+ Researchers are eligible to apply to the CTN+. To become a CTN+ Researcher, an applicant must be qualified (as outlined in the CTN+ Researcher Application Form) and agree to the terms outlined on the CTN+ Researcher Affiliation Agreement. See the *Become a CTN+ Researcher* (https://www.ctnplus.ca/join/) *or Postdoctoral Fellow* (https://www.ctnplus.ca/postdoctoral-fellows/) links on the CTN+ website.

CTN+ Review Committees
Community Leadership Team: The CLT is a broadly representative group of people from across Canada who are living with HIV/STBBIs and/or representing organizations fighting the epidemic. This committee reviews all protocols and informed consent forms submitted to the Network and makes recommendations to the Steering

Committee. It also advises the Scientific Review Committee and CTN+ Researchers and informs the Steering Committee about the research priorities and concerns of Canadians living with HIV or other STBBIs.

Scientific Review Committee (SRC): Scientists, physicians, and members of the HIV and STBBI community are represented on this committee, which makes recommendations to the Steering Committee. Members meet three times yearly to provide peer-reviews of proposals submitted to the CTN+. They evaluate the scientific merit of experimental therapies, as well as the design of trial protocols to ensure that all CTN+ trials are relevant and based on validated methodology.

Steering Committee (SC): This expert group of scientists, people living with HIV, and other stakeholders serves as the CTN+'s Board of Directors. Drawing on its broad range of expertise and knowledge of national and international trends, members consider the recommendations of other Network committees and may set research priorities.

Resource Allocation Committee (RAC): The RAC determines the CTN+'s resource allocation to CTN+ approved projects. These resources may be in-kind or a cost-recovery service that is budgeted into their grant application. All projects must already have a primary source of funds before they are submitted for CTN+ review and approval, with the exception of projects submitted to the Seed Funding competition.

Data Safety and Monitoring Committee (DSMC): Experts in HIV/STBBI clinical care, research design, biostatistics, and law are among the members of the DSMC. The DSMC meets twice per year to monitor the safety and efficacy of CTN+ approved interventional studies in progress, in particular, clinical trials. Applicants may request this service if their study does not have its own DSMC. The committee will also occasionally review preliminary analyses of study results or new information and recommend changes in protocol, procedures, or the termination of a study.

Appendix B: Concept & Full Application Content Requirements

Concept Submissions

The first step towards recognition as a CTN+ Seed Funding Study is the submission of a Seed Funding Concept Form. The concept form is hosted online on the CTN+ Apply platform.

A complete concept form requires the following details:

Applicant Details

1. Full name, email address, and institutional affiliation of the Principal Applicant;
2. Confirmation that the applicant is either a CTN+ Researcher or a postdoctoral fellow under the supervision of a CTN+ Researcher;
3. Confirmation that the applicant is an Early Career Researcher within their first 10 years of independent research activity, or a postdoctoral fellow;
4. Full name and email address of the submitter, if the form is submitted by someone other than the Principal Applicant.

Study Details

1. Title of the study;
2. Name of the study lead, as well as full names, institutions and roles of all study team members;
3. The study's affiliation with a CTN+ Region and a CTN+ Think Tank;
4. Study hypothesis
5. Summary of the study proposal (500 words max.)

Once submitted, each CTN+ Regional Leadership Team will have the ability to support or reject individual study concepts based on their alignment with the Regional Priorities, as well as the Network's Scientific Priorities.

Concepts that receive approval from their Region are then invited to complete a full submission.

Full Submissions

Access to the full submission form is provided through the Apply online platform. Any applicants that received regional approval will be able to access the form through their application dashboard in Apply, and will additionally receive an email notification with access details.

A complete full submission form requires the following details:

Applicant Details

- All applicant details are carried over from the Concept Form, though can be adjusted before submission, if necessary.

Study Details

- Some study details are carried over from the Concept Form: Study title, name of study lead, and list of study team members.
- Selection of the study type:
  - Preclinical
  - Qualitative
  - Epidemiological/Observational
  - Interventional
  - Feasibility
  - Other (requires specification)
- Research question, summarized in one sentence;
- Lay language description (250 words max.);
- Number of study participants;
- List of participating sites, including the research team for each site;
- Rationale explaining the need for seed funding for this study, the feasibility of completing the study in one year, and how this study will support/inform future planning of a larger study, interventions or grant application (750 words max.);
- Summary of the following aspects (2,000 words max.):
  - Primary and secondary objective(s)
  - Study population and inclusion criteria
  - Exposure or intervention (if applicable)
  - Primary and secondary outcomes/measures
  - Analysis plan, including sample size justification and power calculation, if applicable)
  - Recruitment plan
  - Expected results and plan for using results
- Overview of additional resources provided by a supervisor or sponsoring institution, if applicable (200 words max.);
- An upload of your budget document, including an itemized line for all requested funds;

- List of in-kind services requested from your CTN+ Region or National Centre, including Data Management / Databases, Statistics & Methodology, Knowledge Mobilization, and other services (requires specification);
- Overview of study milestones, including the estimated start date and the duration of the study, up to one year (500 words max.);
- List of barriers and potential risks that could impede the study, including mitigation strategies (500 words max.);
- Publication plans (250 words max.);
- Overview of community engagement during project development (250 words max.);
- Demonstration of the study's core commitment to Equity, Diversity, Inclusion, Accessibility, and Justice (250 words max.)

Submitted applications will be evaluated along scientific, methodological, and community-oriented criteria by the CTN+ Review Panel before final adjudication at the next CTN+ Steering Committee meeting. Once a decision has been made, applicants will receive a separate email with the notice of decision and other pertinent details.