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

Portfolio Study Submission and Review Process Guidance

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

- The CTN+ at 778-990-5372 or by email to submissions@hivnet.ubc.ca.

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Overview

The CTN+ Portfolio Study Submission process occurs three times per year and is open to CTN+ Researchers who are in the process of seeking a primary source of funding for their project.

The project must be:

1. interventional; and
2. align to the CTN's current scientific priorities (see appended Glossary of Terms) as approved by the relevant CTN+ Regional Co-Leads.

CTN+ Portfolio Submissions Steps

Step 1: Review the CTN+ Submission Calendar for deadlines (while the Portfolio Study Submission deadlines are aligned with the CIHR Project Grant timelines, other types of grant applications can use the process to request a Letter of Support for other types of grants except Team Grants).

Step 2: Using the online application system, request a CTN+ Letter of Support (LoS) for Portfolio studies within the timelines outlined in the calendar. **The CTN+ Researcher must request a CTN+ Letter of Support (LoS) 8 weeks before grant application date to be eligible for this competition.**

- At the LoS phase for Portfolio Studies, CTN+ Researchers may receive methodology, community, knowledge mobilization, Indigenous Guidance Council, and regulatory consultation (as required) to help strengthen their grant application.
- CTN+ Researchers will request a cost-recovery estimate to include in their grant budget for CTN+ services such as statistics, methodology, database, data management, and advanced knowledge mobilization support
- A full list of in-kind and cost-recovery services available to CTN+ studies can be accessed here
- Regions and Think Tanks will be informed about submissions to this competition from their respective regions and/or related to a specific Think Tank

The CTN+ LoS will be provided to the applicant approximately three to five days before the grant application is due, or on a different date, if specified by the applicant.

Step 3: Successful grant Notice of Decision

1) Use Apply to upload Notice of Decision, budget confirmation, reviewers' comments, and the grant research proposal.
2) Review the CTN+ Submission Calendar for the Portfolio application deadlines and enter Apply to complete the Portfolio Application Form for review by the CTN+.
3) The Review panel (see Glossary of Terms for additional details about the review panel) reviews applications, approved applications are forwarded to the CTN+ Steering Committee and Research Allocation Committee for CTN+ approval and provision of in-kind CTN+ Services.

Step 4:

4) Successful applicants are provided with an Award Letter, CTN+ review comments, and introduced to the relevant Regional Project Manager and grant support service providers to conduct a CTN+ Portfolio Study Kick-off meeting.

CTN+ Portfolio Study Clinical Research Services

LoS phase (before grant submission):

Brief consultation, as required, for: methodology, community engagement, knowledge mobilization, Indigenous Guidance Circle, and regulatory support for Health Canada Clinical Trial Applications. The purpose of the consultations is to assist CTN+ Researchers with strengthening their grant applications.

Full Submission

CTN+ Researchers are able to request both in-kind and cost-recovery services in their full CTN+ submission. See the CTN+ Services List for more information.

Project Eligibility

a. Only CTN+ Researchers who are seeking a primary source of funding for their study may submit to the CTN+ for a LoS.
b. The CTN+ Researcher must adhere to the deadlines as published in the CTN+ Submission Calendar.
c. New projects must align with the CTN+'s scientific priorities (see Glossary of Terms or here). If the project does not align with the priorities, but is innovative, the applicant must be prepared to justify, to the relevant Regional Co-leads, why their respective Region should support the project.
d. To be eligible, a project must have an intervention. The following types of study proposals are encouraged:
    - Multi-centred clinical trials/research studies;
    - Cohort studies (a study assessing clinical outcomes that follows the same people over multiple time points), but only national, multi-centred observational studies that have been peer-reviewed, approved, and fully funded by another funding agency;
    - Pilot studies (a study assessing the feasibility, acceptability and/or effectiveness of an intervention or treatment) that do not fit the criteria for the CTN+ Seed Study Funding Program, and if single-centred, justification must be provided;
    - Implementation science projects, preferably multi-centred and with a focus on health care innovation;
    - Community-based participatory research that aligns with the scientific priorities; and
    - Novel methodologies that advance the field will also be considered

The following types of study proposals are not eligible:

- Basic science or lab-based studies that do not include any clinical research in humans;
- CIHR Team Grants;
- 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

Process

8 weeks before the CIHR Project Grant (or other grant types) Deadline

CTN+ Researchers must enter Apply to request a LoS to apply to this competition. The same process will be used for all grant application (aside from Team Grants) to obtain a LoS. If you have questions, you can reach Erin Cherban at 778-990-5372 or email submissions@hivnet.ubc.ca.

At the LoS stage, all projects are eligible for a methodology, community, Health Canada regulatory, knowledge mobilization, and Indigenous Guidance Circle consultation. The purpose for this brief consultation at this stage is: to provide feedback to improve your grant application and estimates for grant cost-recovery services to add to your grant budget; enable the Regional Co-Leads the opportunity to determine if the proposed study aligns with the CTN+ Scientific Principles; inform the Regions and Think Tanks about the pending application; and provide the CTN+ with real time information about prospective new studies. See the CTN+ Services List for an overview of the in-kind and cost-recovery service matching provision the CTN+ can provide for this competition.

Approximately three to five days to a week prior to your grant application due date, you will receive the CTN+ LoS, unless you requested an earlier deadline in your CTN+ LoS application.

Upon Successful Notice of Decision

Applicants who receive a successful Notice of Decision, for full funding (Bridge funding is not eligible), from CIHR or another granting agency, who have previously received a CTN+ LoS can use Apply to complete a full application. Applicants will be required to upload their successful Notice of Decision, grant budget (including approved amount), reviews, and grant research proposal in addition to completing the online application form.

As published in the CTN+ Submission Calendar, applications will be reviewed by the CTN+ review committee. If approved, the submission will be forwarded to the CTN+ Steering Committee and Research Allocation Committee for CTN+ approval and provision of in-kind and assistance with sourcing the cost-recovery service in one of the CTN+ regions. Applicants will be provided with an award letter that outlines the in-kind and CTN+ Regional location of their cost-recovery services, feedback from the CTN+ Review Committee. In the award letter email, the applicant will also be provided with contact details for their Regional CTN+ Project Manager who will assist the applicant by scheduling the required Study Kick-Off meeting. All service providers for the approved study will attend this meeting.

CTN+ Review Process

The online application is assigned for review by the Community Advisory Committee and Scientific Review Committee (if not previously peer-reviewed in the grant process) reviewers who will meet approximately six weeks after the applications are due. If the submission is approved, it is then reviewed by the CTN+'s Steering Committee (for approval) and the Resource Allocation Committee (for resource allocation) and the applicant is provided with an award letter that outlines the in-kind and fee-for-service resources provided from the CTN+.

All committee members are bound by confidentiality agreements. Information about the review committees may be found at in the appended Glossary of Terms or on the CTN+ website.

Post-Approval Process

Within six weeks of the reviews, the applicant will receive an award letter from the National Director that outlines the results of the reviews and describes the resource allocation. Successful applicants are required to respond to CAC and SRC required/recommended changes, in writing. The Steering Committee and Resource Allocation Committee may also request additional details from applicants. **CTN+ in-kind services and services (fee-based) will not be allocated to the project until the applicant(s) have provided their written responses to the Review Committees, and the committees are satisfied with the responses.**

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 online and are provided to successful applicants.

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

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 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 eligible to apply to the CTN+. To become a CTN+ Researchers, 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 CTN+ website for more information.

CTN Review Committees
Community Advisory Committee (CAC): The CAC 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.

Research 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.

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.

CTN+ Scientific Priorities

Principles that are included in all themes:

- Focus areas are HIV, STBBI and emerging infections in our key populations;
- Key populations include:
    i. Indigenous Peoples
    ii. Gay, bisexual and other Men who have sex with men (GBM)
    iii. People from countries with a high prevalence of HIV/STBBIs
    iv. People with mental health challenges
    v. People who use drugs (PWUD)
    vi. Women (cis and transgender women)
    vii. Children affected by HIV and STBBIs
    viii. Gender minorities
    ix. People with episodic vulnerabilities (for example, prisoners)
    x. People with disabilities
- A renewed commitment to Reconciliation, community engagement, breaking down stigma, and incorporating lessons learned from the COVID-19 pandemic as the CTN+ will continue to provide an inclusive, positive, and collaborative environment for all communities; and
- Partnering with key population, public health, advocacy and service organizations.

The scientific priorities of the CTN+ are as follows:

1) Prevention and Testing

a. Developing and testing interventions for STBBI prevention and harm reduction
b. Developing and testing strategies for early detection of HIV, HCV, HPV, syphilis, and other STBBI

2) Optimizing Health Outcomes

a. The role of inflammation, major organ dysfunction, antiretroviral agents, genetics, the microbiome, viral co-infection, alcohol, drug use, mental health, behavioural and/or social factors on health outcomes, and elucidating novel treatment targets
b. Intervention strategies to improve health outcomes for persons living and aging with HIV, STBBIs, and emerging infections

3) Cure

a. Innovative approaches to cures for HIV and STBBIs: This may include, but is not limited to, strategies to impact immune activation and depletion of viral reservoirs

4) Methods

a. Advancing innovative trial methods that involve priority populations;
b. Advancing implementation science methods to enable scale up of successful models of care in other settings

However, all innovative research that advances the field will also be considered.

Types of Submissions

There are two types of submissions:

- Initial Proposal — These are new submissions that were approved, after LoS registration and upon successfully receiving grant funding for a full review by the CTN+
- Re-submissions — These are submissions that were previously reviewed and not approved by the CTN+