



the CTN
CIHR Canadian
HIV Trials Network

le Réseau
Réseau canadien
pour les essais VIH des IRSC

CIHR Canadian HIV Trials Network (CTN) Pilot Study Funding Program Guidance Document



A. Introduction & Objective

The CTN Pilot Study Funding Program was implemented, at the request of Network Investigators, to provide funding for pilot or proof-of-concept studies. Funding for these types of studies is difficult to obtain and these studies are required to determine the feasibility, acceptability, sample size and/or otherwise inform the development of an adequately statistically powered, larger study.

The Program was initiated in 2010 and was followed by four additional annual competitions until the Program was halted for review and reinitiated in 2016. Studies are supported with a cash contribution of up to \$50,000 and are eligible for a maximum of \$50,000 of in-kind services from the CTN National Centre. 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.

An additional purpose of this Program is to provide training and mentorship opportunities for junior investigators to gain experience by working with senior investigators across the Network and with National Centre staff for support services on how to run an intervention/clinical trial or how to implement a research project. The Program is only open to CTN Investigators who are within ten years of their first university appointment or professional position or fellows/trainees who are supervised by a CTN Investigator (the supervising CTN Investigator must meet the criteria to hold funds at their home institution). Please note that current CTN Postdoctoral Fellowship Awards program awardees are eligible to apply, however, their funds must be held by the CTN Investigator who is their supervisor.

It is anticipated that this Program will occur once per year. The competition will be announced on the CTN website at: <http://www.hivnet.ubc.ca> and it should be noted that CTN Investigators who are not eligible for this particular Program, and who wish for CTN review of pilot or proof-of-concept studies, may use the regular CTN application process. Please refer to: <http://www.hivnet.ubc.ca/research-services/studysubmission/> to review the application process for regular CTN studies.

** Please see Appendix A for a list of definitions related to this Program*

Objective*

In summary, the Program is intended to provide the following:

- Sole funding for all direct costs for new pilot or proof of concept studies with high scientific/ medical merit;
- Data and feasibility information to support the development of a randomized controlled trial (RCT) or larger study;
- Approval of new studies that will be initiated within 12 months of the award. If merited, only one extension will be granted and if the study is not initiated within 18 months, the award must be returned to the CTN;
- Mentorship opportunity for junior investigators (including both CTN Postdoctoral Fellows and non-CTN Postdoctoral Fellows) to work with senior CTN Investigators; and
- An opportunity for the CTN National Centre personnel to mentor junior investigators in study design, regulatory and operational requirements.
- **NEW:** pilot projects for COVID-19 that involve people living with HIV/HCV/STBBIs are eligible for submission this year.



This Program will not:

- Provide funds/services to existing studies;
- Provide funds/services to studies that have other sources of funding for the direct study costs/services;
- Provide funds for equipment, computers, archiving or archiving services;
- Fund studies led by researchers who are not CTN Investigators;
- Provide funds for CTN Investigators who were in their first position ten or more years ago (unless you are able to provide documented proof of leave). Current CTN Postdoctoral Fellows who receive financial support from the CTN Postdoctoral Fellowship Awards program are eligible to apply, however, their funds must be held by the CTN Investigator who is their supervisor (it is anticipated that this CTN Investigator was in their first position more than ten years ago). Postdoctoral Fellows who are supervised by a CTN investigator, but who are not CTN Postdoctoral Fellows are eligible, but they must provide proof that they are currently enrolled in a formal academic program and their funds will also be held by the CTN Investigator who is their supervisor.
- Provide in-kind services in excess of \$50,000, the level of service required will be determined during the evaluation of the study and studies that exceed this level of service will be rejected, unless the candidate's home institution agrees to provide additional, in-kind services to support the study. The CTN National Centre will work with personnel to ensure that service provision is capped accordingly.

** Please see Appendix A for a list of definitions related to this Program*

B. Scientific Priorities of the CTN

To assist you with determining if this Program aligns with your current research interests, additional details about the CTN's Cores, which provide the mechanism for supporting the development of new concepts and studies, and the CTN's current scientific priorities are provided below.

Cores

The CTN has four scientific Cores. This structure has been designed to support our scientists – emerging and experienced – to generate new concepts and protocols. The Cores strive to ensure that the studies that are implemented remain focused on key scientific priorities while also providing flexibility to address new scientific topics as they emerge. The Core 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 Cores are:

- a) Clinical Care & Management (CCM)
- b) Co-Infections & Related Conditions (CRC)
- c) Vaccines & Immunotherapies (VIT)
- d) Prevention (PREV)

Each Core is led by two Co-leads. Please email submissions@hivnet.ubc.ca if you require an introduction to the applicable Core Co-leads.



Together, these teams function as a catalyst for scientific activity within their focus areas. Core teams concentrate the expertise of multidisciplinary personnel such as clinical investigators and nurses, clinical research coordinators, CTN support staff, and members of the HIV community, to generate study protocols that address the most urgent, emerging clinical questions, while keeping scientific discovery focused on the CTN's scientific priorities.

Scientific Priorities

Principles that are included in all themes:

- Focus areas are HIV and STBBIs;
- Key populations include:
 - i. Indigenous Peoples
 - ii. Men who have sex with men (MSM)
 - iii. People from HIV/STBBI-endemic countries
 - iv. People with mental health challenges
 - v. People who use (inject) drugs (PWUD)
- Community engagement as the CTN wishes to continue to provide an inclusive, positive, and collaborative environment for all communities; and
- Partnering with key population advocacy and service organizations.

1) Prevention

- a. Developing and testing interventions for prevention and harm reduction (for example, PrEP).
- b. Developing and testing strategies for early detection and treatment of HIV, HCV, HPV, syphilis, and other STBBIs.

2) Optimizing Health Outcomes

- a. A focus on treatment strategies and improving health outcomes for persons living and aging with HIV and STBBIs. This includes:
 - i. Developing interventions to decrease the risk of comorbidity and death while improving health outcomes and decreasing health disparities.
 - ii. Assessment of the role of inflammation, major organ dysfunction, antiretroviral agents, genetics, the microbiome, viral co-infection, alcohol, drug use, and/or lifestyle factors on the risk of co-morbidity and cancer.

3) Cure

- a. Collaborating with basic sciences to study innovative approaches to seek cures for HIV: this may include, but is not limited to, strategies to impact immune activation and depletion of viral reservoirs.

C. CTN Pilot Study Funding Program Guidelines Process

A) Interested candidates who fulfill the Program requirements should read the Guidance Document, complete the Concept Submission Form and contact one or both Core Co-leads from the CTN Core relevant to their concept*. The Core Co-lead will provide the candidate with guidance, ensure the concept aligns with the CTN's scientific focus areas outlined on the Concept Submission Form and sign



off on the concept submission form. For assistance contacting the appropriate Core Co-lead, please email submissions@hivnet.ubc.ca

** Please see Appendix A for a list of definitions related to this Program*

B) The Core Co-leads will meet by conference call to vet the Concept Submission Forms and recommend a short-list of concepts for full submission.

C) The CTN will invite the candidates with the short-listed concepts to submit a full proposal. The CTN will provide the full submission form to the candidates for completion.

D) The candidates must complete the full application and should liaise (email submissions@hivnet.ubc.ca as required) with the applicable Core Co-lead and the CTN National Centre while completing the application.

E) A CTN sub-committee, chaired by the Scientific Review Committee chair person and comprised of at least one Community Advisory Committee member, a statistician/ methodologist, a clinician or other relevant expert, the CTN's Chief Clinical Research Officer, the Data Management Operations Lead, the Chief Administrative Officer and, potentially, the Director of Regulatory Affairs will review the full submissions using the details outlined below.

F) Applicants will be notified and successful applicants will be notified about the amount of financial and in-kind support they will receive and will then work with the applicable Core and CTN National Centre to begin their pilot study.

D. Application Forms

Stage 1 – Core Co-lead Triage

- Applicants must complete the Pilot Funding Study Program Concept Submission Form and submit as a PDF with their CV to submissions@hivnet.ubc.ca
- Detailed instructions for applicants are included on the form.
- The form is located on the CTN website in “CTN Review Phase” of the Research Toolbox: [Research Toolbox | CIHR Canadian HIV Trials Network \(ubc.ca\)](#)

Stage 2 – Full Pilot Study Proposal Submission

- As outlined in section C above, those applicants with concepts that are short-listed by the Core Co-leads will be invited by the CTN to submit a full proposal.
- Detailed instructions will be included on the form and the form will be emailed to the short-listed applicants.
- Each applicant will be provided with publications about Pilot Studies to assist them in preparing their proposal.
- Applications must include a detailed budget for use of funds and request the in-kind services they require.
- The applicant must continue to liaise with the appropriate Core Co-lead (or designate from the applicable Core) while they prepare their application and similar to the Concept Submission phase, they must include the name of the Core-Co-lead on their application.



- Applicants are encouraged to discuss their in-kind service requirements with the CTN National Centre, by emailing submissions@hivnet.ubc.ca while they prepare their full submission.

E. Full Pilot Proposal Review

As outlined in Section C, a CTN sub-committee, chaired by the Scientific Review Committee chair and comprised of at least one Community Advisory Committee member, a statistician/ methodologist, a clinician or other relevant expert, the CTN's Chief Clinical Research Officer, the Data Management Operations Lead, the Chief Administrative Officer and potentially the Director of Regulatory Affairs, will review the full submissions.

The following set of criteria may be used to assess applications:

- Demonstration of clinical/scientific merit
- Potential impact in terms of:
 - a) Patient-related outcomes;
 - b) contributions to the CTN's scientific priority areas* and/or;
 - c) new and emerging research areas.
- Feasibility of implementation and execution
 - Clarity of objectives
 - Likelihood of gathering data to inform a larger study
 - Potential for initiation within 12 months of receiving funds
 - Achievable solely with funding awarded from the Program
- Preference is given to interventional studies

** Please see Appendix A for a list of definitions related to this Program*

F. Post-Award Announcement Process

A) Applicants will be notified by the CTN National Centre if their application was successful (eligible for funds and in-kind services) or not successful. Successful applicants will receive confirmation of the award amount and the in-kind services to be provided, along with the study lead's responsibilities and reporting requirements.

B) The financial award will be provided in two separate payments. The initial payment will be released when the project is approved by the CTN and the award letter is complete (note: a contract between the CTN National Centre and the applicant's home institution may be required). The second payment will be provided once the submission of a progress report at the request of the CTN is complete.

C) Studies must be initiated within 12 months of award; if merited, only one extension will be granted and if the study is not initiated within 18 months, the award must be returned to the CTN.

D) Awardees must develop the pilot study in consultation with an appropriate CTN Core and their supervisor (if applicable).

E) The awardee must provide updates about the progress of the Pilot Study when requested, for example, for the Core meetings during the CTN's annual meetings or when requested by the CTN National Centre.



F) During the pilot study and upon completion, awardees are encouraged to publish or present their findings and adhere to the CTN's publication policy (the policy will be emailed to successful applicants).

G. Guidance Document

This guidance document will be reviewed and updated as required. New versions will include the most recent date, they will be posted on the CTN website and a notation that outlines the most recent version date will be included to provide clarity to applicants.



APPENDIX A - Definitions

To prevent confusion, definitions for the wording used in this Program are listed below.

The Program is only open to CTN Investigators who are within ten years of their first university appointment or professional position or fellows (Post-Doctoral Fellows only) who are supervised by a CTN Investigator (the supervising CTN Investigator must meet the criteria to hold funds at their home institution). All non-CTN postdoctoral fellows must provide proof that they are currently enrolled in a formal academic program when their Concept Form is submitted.

All candidates must submit a CV with their Concept Submission Form. As noted, CTN Investigators must be within ten years of their first university appointment or professional position (candidates who have taken leave must provide a note which explains the amount of time that was required for the leave).

Fellows/trainees who are supervised by a CTN Investigator must provide proof that their supervisor is one of their primary academic supervisors and their supervisor must meet the criteria for holding funds at their home institution. To attest to these requirements, supervisors must sign the Concept Submission Form.

Please note that current CTN Postdoctoral Fellows who receive financial support from the CTN Postdoctoral Fellowship Awards program are eligible to apply, however, their funds must be held by the CTN Investigator who is their supervisor.

CTN Cores - The CTN has four scientific Cores, this structure has been designed to support our scientists – emerging and experienced – to generate new concepts and protocols. The Cores strive to ensure that the studies that are implemented remain focused on key scientific priorities while also providing flexibility to address new scientific topics as they emerge. The Core 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 Cores are:

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- 3) Vaccines & Immunotherapies (VIT)
- 4) Prevention (PREV)

Each Core is led by two Co-leads.

Scientific Priorities

Principles that are included in all themes:

- Focus areas are HIV and STBBIs;
- Key populations include:
 - i. Indigenous Peoples
 - ii. Men who have sex with men (MSM)
 - iii. People from HIV/STBBI-endemic countries
 - iv. People with mental health challenges
 - v. People who use (inject) drugs (PWUD)



- Community engagement as the CTN wishes to continue to provide an inclusive, positive, and collaborative environment for all communities; and
- Partnering with key population advocacy and service organizations.

1) Prevention

- a. Developing and testing interventions for prevention and harm reduction (for example, PrEP).
- b. Developing and testing strategies for early detection and treatment of HIV, HCV, HPV, syphilis, and other STBBIs.

2) Optimizing Health Outcomes

- a. A focus on treatment strategies and improving health outcomes for persons living and aging with HIV and STBBIs. This includes:
 - iii. Developing interventions to decrease the risk of comorbidity and death while improving health outcomes and decreasing health disparities.
 - iv. Assessment of the role of inflammation, major organ dysfunction, antiretroviral agents, genetics, the microbiome, viral co-infection, alcohol, drug use, and/or lifestyle factors on the risk of co-morbidity and cancer.

3) Cure

- a. Collaborating with basic sciences to study innovative approaches to seek cures for HIV: this may include, but is not limited to, strategies to impact immune activation and depletion of viral reservoirs.

Sole funding – Pilot and proof-of-concept studies approved within this Program cannot have any other source of monetary support to be eligible for this Program.

New projects - This Program is targeted to support new projects that are pilot or proof-of-concept studies that are expected to generate data to inform the development of a larger study. Applications from existing projects seeking top-up funding will not be accepted.

In-Kind Services – The CTN National Centre will evaluate each application and approve a maximum of \$50,000 of in-kind services. These services may include:

- Regulatory affairs for Clinical Trial Applications to Health Canada only;
- Statistical and methodological consultation for study design and reporting;
- Monitoring as required by Health Canada-regulated studies only, any additional monitoring must be completed by the candidate.
- Protocol and informed consent design, project management, recruitment plan, budget development (institutional grant and budget requirements must be fulfilled by the candidate) and study operational guidance are provided for study start up only, the candidate is expected to manage the study and provide reporting (including financial reporting) to their designated CTN project manager for the duration of the study at pre-determined reporting intervals;
- Data management consultation for the development of case report forms and database set up during start up only, the candidate is expected to enter, manage and clean their own data.
- Pharmacoeconomics analysis;
- Access to the CTN's Communications and Knowledge Translation department; and



- If required, review by the CTN's Data and Safety Monitoring Committee.

The candidate is required to complete all the necessary requirements for their home institution, these include:

- Fulfilling their institutional Research Ethics Board requirements and will be requested to complete clinical trial registration, if applicable;
- Observe the progress of contract negotiation between their home institution and the CTN National Centre and respond 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 Centre with financial statements as required.

The candidate is free to request these types of in-kind services from their home institution and if the CTN National Centre personnel determines that the in-kind services required exceed the \$50,000 maximum, to qualify for funding, the candidate will be required to provide written proof that their home institution will provide the services.