MINISTRY OF MENTAL HEALTH AND ADDICTIONS
INFORMATION BRIEFING NOTE

Cliff # 1102838

PREPARED FOR: Honourable Minister Judy Darcy - **FOR INFORMATION**

TITLE: Update on pilot to provide low-barrier oral hydromorphone to prevent fatal overdoses

PURPOSE: To provide Minister Darcy with updated information on a Health Canada funded proposal to provide low-barrier oral hydromorphone to prevent fatal overdoses

BACKGROUND:
BC continues to grapple with a troubling public health emergency related to illegal drug overdoses and overdose deaths, with over 1,400 deaths likely recorded in 2017 alone. In escalating its response to the crisis, the province has established the Overdose Emergency Response Centre (OERC) and is working across sectors and across government to identify innovative strategies to help prevent overdoses and overdose deaths.

In November 2017, the Minister was provided with information (see Cliff 1096870) on a proposed low-barrier, scalable pilot to provide oral hydromorphone to rapidly expand access to pharmaceutical-grade opioids as an alternative to the toxic illegal drug supply. Dr. Mark Tyndall of the BC Centre for Disease Control has since received funding from Health Canada's Substance Use and Addictions Program to pilot this project.

DISCUSSION:
There is considerable work to be done ahead of implementing this pilot, including:

- engaging with the College of Physicians and Surgeons of BC (responsible for providing approval to prescribe off-label use of oral hydromorphone);
- engaging with and the College of Pharmacists of BC (responsible for overseeing dispensing methods of oral hydromorphone);
- selecting a pilot location (with Vancouver being one of the likely choices);
- determining clinical criteria and recruitment process for participants;
- establishing a rigorous evaluation plan;
- obtaining ethical approval from the University of British Columbia; and
- determining how to store and distribute oral hydromorphone.

There has been focus by the media and Vancouver City Council that the pilot would potentially utilize vending machines to dispense oral hydromorphone. Dr. Tyndall has been solicited by a private company developing a vending machine model to potentially dispense recreational cannabis; however, there is no confirmation that this model would function as purported, and this type of machine is only one possible way of dispensing oral hydromorphone. The pilot will test several models for safety, accessibility and feasibility including:

- Distribution through a community pharmacist;

- Distribution through secure dispensing machines in supportive housing sites, overdose prevention sites and/or supervised consumption sites; and/or
- Distribution through outreach nursing/nursing in supportive housing sites, overdose prevention sites and/or supervised consumption sites.

There is concern by the OERC and Dr. Tyndall that a recent presentation to Vancouver City Council left the impression that the pilot is asking for the City to take action in relation to this pilot; this is not the case, rather, Dr. Tyndall is only asking for support, in principle, from Council.

ADVICE:
The Overdose Emergency Response Centre is working with Dr. Tyndall to support this low-barrier pilot project. Research and evaluation of the pilot will help identify the physician, nursing and pharmacy costs as well as the daily dose of oral hydromorphone required by most clients. Research will also identify scalable model(s), address safety and accessibility concerns, and account for lives saved.

s.13

Program ED/Division: Carolyn Davison
Telephone: 250-952-3674
Program Contact (for content): Haley Miller
Date: January 22, 2018

MINISTRY OF MENTAL HEALTH AND ADDICTIONS
DECISION BRIEFING NOTE

Cliff # 1095143

PREPARED FOR: Honourable Minister Judy Darcy - **FOR DECISION**

TITLE: Comment on Amendments to the Federal Narcotic Control Regulation to Facilitate Distribution of Diacetylmorphine – **deadline January 9, 2018**

PURPOSE: Decision on signing a letter to federal Health Minister supporting proposed amendments to the federal Narcotic Control Regulation to treat diacetylmorphine in the same manner as other opioid agonist medications.

BACKGROUND:
On October 10, 2017, Minister Darcy approved the BC Centre on Substance Use guidance for hydromorphone treatment and directed all health authorities to submit their plans for implementation of hydromorphone-based injectable OAT (iOAT) in British Columbia.

Internationally, injectable pharmaceutical-grade diacetylmorphine (DAM), also known as heroin, is used as a clinically and cost effective medication for iOAT; two well-designed Canadian Institutes of Health Research-funded randomized clinical trials in Vancouver's Crosstown Clinic, operated by Providence Health Care and demonstrated the effectiveness and safety of DAM for treatment-refractory patients (NAOMI[i] and SALOME[ii] trials). Many patients at the clinic continue to receive DAM treatment, notwithstanding complex regulatory requirements. Current plans for expansion of iOAT in BC contemplate using readily available hydromorphone, which the SALOME trail demonstrated was a non-inferior alternative to diacetylmorphine; however, federal modernization of the regulatory status of DAM could result in important feasibility improvements should BC consider expanding use of DAM in the future. The practical availability of more than one non-inferior treatment can also lead to competitive pricing by pharmaceutical manufacturers.

DISCUSSION:
An important difference between DAM and other pharmaceutical opioids used for opioid agonist treatment (for example, injectable hydromorphone) lies in the regulatory framework governing DAM, which is not manufactured in Canada. Additional complex regulatory requirements for the importation, distribution, storage and use of DAM complicate consideration of any expansion of DAM treatment beyond the Crosstown Clinic. In particular, the current version of the federal Narcotic Control Regulation restricts DAM use to hospital settings (see Appendix 1). This precludes use of DAM in all health care settings not run as outpatient clinics by hospitals—an obstacle to anyone not living near a hospital facility.

In June, 2017 Health Canada passed new regulations which included publishing a list of drugs for an urgent public health need, including DAM. Publication of this list has removed some barriers to importation and distribution of DAM.

On November 11, Health Canada announced a consultation on its intent to remove current Narcotic Control Regulation requirements preventing consideration of use of

DAM in community based clinics (Appendix 2), with a response **deadline of January 9, 2018**. The announcement noted that the proposed changes could increase opportunities for diacetylmorphine-assisted treatment as part of a comprehensive treatment plan and that Health Canada is committed to supporting better treatment options by facilitating access to treatments for opioid use disorder. Along with recent removal of DAM importation barriers, these proposed regulatory changes, if passed, could support realistic future consideration of DAM treatment beyond Providence Health's Crosstown Clinic.

OPTIONS:

Option 1. Minister agrees with Health Canada's intent to remove the federal limitations on DAM to hospital settings and sends a letter in support (draft letter in Appendix 3).

> **Pros**: Removal of regulatory barriers will allow future consideration of expanded expansion DAM treatment in BC—in community settings rather than just hospital outpatient settings; aligns with previous communications between Ministry staff and Health Canada regarding the need to modernize the DAM regulatory framework.
> **Cons:** expansion of DAM into non-hospital settings could require considering alternate funding to purchase and distribute the medication, similar to injectable hydromorphone.

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FINANCIAL IMPLICATIONS: Not applicable.

RECOMMENDATION: Option 1

Judy Darcy

January 24, 2018

Approved/Not Approved
Honourable Judy Darcy
Minister

Date Signed

Program ADM/Division: Mary Sue Maloughney /Warren O'Briain
Telephone: 250 952-1531
Program Contact (for content): Mikhail Torban
Drafter: Brian Emerson and Mikhail Torban
Date: December 29, 2017

References

[i] Oviedo-Joekes, E., Nosyk, B., Brissette, S., Chettiar, J., Schneeberger, P., Marsh, D. C.,Schechter, M. T. (2008). The North American Opiate Medication Initiative (NAOMI): Profile of Participants in North America's First Trial of Heroin-Assisted Treatment. Journal of Urban Health : Bulletin of the New York Academy of Medicine, 85(6), 812–825.

[ii] Oviedo-Joekes E et al. (2015). The SALOME study: recruitment experiences in a clinical trial offering injectable diacetylmorphine and hydromorphone for opioid dependency. Subst Abuse Treat Prev Policy.
10: 3. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4355145

BRITISH COLUMBIA

JAN 24 2018

1095143

The Honourable Ginette Petitpas Taylor, PC, MP
Minister of Health
70 Colombine Driveway
Tunney's Pasture
Postal Location: 0906C
Ottawa, Ontario K1A 0K9

Dear Minister Petitpas Taylor:

As you are aware, British Columbia is experiencing one of the most tragic health crises of our time. In 2016 the BC Coroners Service reported that 978 people died from unintentional illegal drug overdoses, numbers unprecedented in our province's history. In spite of our best efforts, in the first 10 months of 2017 a further 1,208 people died from unintentional illegal drug overdose.

BC declared a public health emergency in April 2016, and is taking wide-ranging action with partners across the health and public safety sectors to prevent as many future tragedies as possible. One of the directions of this provincial response to the opioid overdose crisis is to expand access to evidence-based treatments for opioid substance use disorder, including injectable opioid agonist treatment (iOAT) with diacetylmorphine (DAM).

Currently, complex regulatory requirements associated with the importation, distribution, storage and use of DAM complicate expansion of iOAT with DAM in BC. Under the Narcotic Control Regulations (NCR), DAM use is limited to hospital settings and can only be prescribed to in-patients or out-patients of a hospital (See Diacetylmorphine Regulatory Requirements, attached).

We believe that DAM should be treated in the same manner as other prescription opioids agonist treatment medications so that it can be used in community settings, under appropriate oversight and supervision. Therefore we support removal of the regulatory restrictions specific to DAM in the NCR as outlined in the Canada Gazette Vol. 151, No. 45. The proposed regulatory changes would remove an important barrier to expansion of DAM treatment in community health care settings in British Columbia.

Thank you for your consideration of this urgent matter, and your willingness to assist us in responding to this unprecedented public health crisis.

Sincerely,

Judy Darcy
Minister of Mental Health and Addictions

cc: ocs_regulatorypolicy-bsc_politiquereglementaire@hc-sc.gc.ca

Diacetylmorphine Regulatory Requirements

Diacetylmorphine is treated as special class of drug under the *Controlled Drugs and Substances Act*, Narcotic Control Regulations (NCR. Specifically a licensed dealer can only provide diacetylmorphine to hospitals, and use is only allowed in a hospital setting by a doctor or dentist (See excerpts below of NCR sections 24 (4), 53 (4) and 65 (7))

Narcotic Control Regulations Excerpts

24 (4) Subject to section 25, a licensed dealer may sell or provide diacetylmorphine (heroin) to

(a) another licensed dealer;

(b) a hospital employee, if that hospital provides care or treatment to persons;

(c) if practising in a hospital, a practitioner of medicine or dentistry, if that hospital provides care or treatment to persons; or

(d) a person exempted under section 56 of the Act with respect to the possession of that narcotic for a scientific purpose.

53(4) A practitioner of medicine, dentistry or veterinary medicine shall not administer diacetylmorphine (heroin) to an animal or to a person who is not an in-patient or out-patient of a hospital providing care or treatment to persons, and shall not prescribe, sell or provide diacetylmorphine (heroin) for an animal or such a person.

65 (7) The person in charge of a hospital providing care or treatment to persons may permit diacetylmorphine (heroin) to be sold, provided or administered to a person under treatment as an in-patient or out-patient of the hospital on receipt of a prescription or a written order signed and dated by a practitioner of medicine or dentistry.

MINISTRY OF MENTAL HEALTH AND ADDICTIONS
INFORMATION BRIEFING NOTE

Cliff # 1096870

PREPARED FOR: Honourable Judy Darcy - **FOR INFORMATION**

TITLE: Low Barrier Oral Hydromorphone to Prevent Fatal Overdoses: BC Centre for Disease Control proposal to the Health Canada Substance Use and Addictions Program

PURPOSE: To inform Minister Darcy about proposal for low barrier oral hydromorphone program being submitted to Health Canada

BACKGROUND:
On April 14, 2016, a public health emergency was declared in British Columbia (BC) in response to the epidemic of opioid overdose deaths. In 2016, 967 people in BC died from overdose due to fentanyl contaminating the illegal drug supply, and evidence suggests we are on track to exceed this death toll in 2017[i]. Urgent action is required to prevent overdose deaths of individuals at risk of overdose. The BC Overdose Action Exchange 2016/2017 report and Vancouver Police Department 2017 report recommended immediate widespread distribution of effective opioid substitution drugs and increased access to a safer drug supply[ii,iii].

In their proposal to the Health Canada Substance Use and Addictions Program (Appendix B), a multi-agency, two province team led by Dr. Mark Tyndall of the BC Centre for Disease Control proposes a low barrier, scalable model of oral hydromorphone distribution to rapidly expand access to pharmaceutical-grade opioids as an alternative to the toxic drug supply responsible for the epidemic of opioid overdose deaths in BC and Alberta.

The proposed project will develop strategies to reach individuals using opioids from the illegal supply, particularly those using alone, as well as those not connected to community or engaged with health services.

Oral hydromorphone tablets proposed for use in the project are inexpensive and easily accessible. Hydromorphone would be prescribed by a physician or registered nurse through delegated authority, dispensed by a community pharmacist, delivered, documented, audited, and stored according to Health Canada and provincial regulations for controlled substances.

Development of the project will include ethics review, consultation with professional Colleges, addictions physicians, health authorities, medical associations, and public safety representatives and peer networks.

DISCUSSION:
Current uses of hydromorphone (HDM) tablets are limited to pain management so the proposed low-barrier harm reduction model falls outside current use indications for oral HDM tablets and will be considered "off-label", which may raise concerns from regulatory bodies. In addition, there may be policy implications with respect to requirements of the federal *Controlled Drugs and Substances Act and Narcotic Control Regulations*, and provincial *Pharmacy Operations and Drug Scheduling Act*. The proposal has built in plans to engage with the relevant regulatory bodies to work through any potential policy implications.

The research will address such questions as to the provision of tablets (containing other components in addition to the drug) for crushing and injecting, rather than using powdered HDM and the use of the most appropriate substance.

The research will also help identify the physician and pharmacy costs as well as daily dose of HDM required by most clients.

Dr. Tindal has expressed an interest to work within the new Overdose Emergency Response Centre structure to undertake this research project. A meeting is being set up in January to have further discussions.

ADVICE:
Continue to engage with Dr. Mark Tyndall and his team to discuss the policy implications of the proposed project.

Program ADM/Division:
Telephone: (250) 952 1003
Program Contact (for content): Carolyn Davison, A/ED, Ministry of Mental Health and Addictions
Drafter: Mikhail Torban, Brian Emerson
Date: December 18, 2017

Appendix A - References

[i] BC Coroners Service (2017) Illicit Drug Overdose Deaths in BC January 1, 2007 - July 31, 2017. Retrieved on October 26, 2017 from http://www2.gov.bc.ca/assets/gov/public-safety-and-emergency-services/death-investigation/statistical/illicit-drug.pdf

[ii] BC Centre for Disease Control (2017) BC Overdose Action Exchange II. Meeting report. Retrieved on October 26, 2017 from http://www.bccdc.ca/resource-gallery/Documents/bccdc-overdose-action-screen.pdf

[iii] Vancouver Police Department (2017) The Opioid Crisis: The Need for Treatment on Demand. Review and recommendations, May 2017. Retrieved on October 26, 2017 from http://vancouver.ca/police/assets/pdf/reports-policies/opioid-crisis.pdf

Health Canada Santé Canada

Substance Use and Addictions Program (SUAP)

FULL PROPOSAL TEMPLATE

INSTRUCTIONS:

This template is the **required** proposal format, to be completed in full. Please ensure that you follow the instructions below:

- Type your responses within the boxes of this template when developing your proposal using the same headings and number system. Attach required documents separately where indicated.
- Guidelines on the length of each section are provided as a guide, not as a firm limit. Depending on the complexity of the proposed project or intervention responses may be shorter than or exceed the guidelines. Responses should be single-spaced, using Size 12 font.
- The proposal assessment criteria embedded in the template should be considered in your responses.

Your funding request package must include the following:

- ☐ Completed original Full Proposal Template signed by an authorized representative of your organization;
- ☐ Evidence of your organization's eligibility. For incorporated organizations: *e.g., copy of your status certificate, incorporation documents (patent letters) or articles of Incorporation.* For unincorporated organizations: *e.g., Terms of Reference or governance structure, provincial/territorial papers, or Board of Director's list.*
- ☐ Copy of documentation confirming status of funding from other sources, if applicable.
- ☐ Copy of employment/labour agreements or equivalent, if applicable.
- ☐ Copy of rental/lease agreement, if applicable.
- ☐ Most recent audited financial statements;
- ☐ Your organization's most recent annual report, if available;
- ☐ Official signed letter from your organization agreeing to support the project; and,
- ☐ Letters of support from confirmed partner organizations stating its role and financial and/or in-kind contributions to the project.

Health Canada collects information for the purpose of evaluating funding applications for grants and/or contributions. The information contained in the Full Proposal Template such as the objectives and activities of the organization, number of employees, and financial data may be accessible under the provisions of the *Access to Information Act*. All personal information will be protected in accordance with the *Privacy Act*.

Substance Use and Addictions Program

SECTION 1 — Organizational Information

1. Language of Correspondence Preferred: ☒ English ☐ French

2. a. Legal Name of Organization: **BC Centre for Disease Control & Prevention Society Branch**
   b. Legal Name of Organization in French (if applicable):
   c. Operating Name of Organization (if different from Legal Name): **BC Centre for Disease Control**

3. Size of Organization
   a. Number of employees: **215 excluding casual employees**
   b. Annual budget: **70 million (2015/16 Fiscal Year)**

4. Mailing Address:	5. Courier Address *(if different than mailing address)*:
BCCDC **655 West 12th Avenue,** **Vancouver BC, V5Z 4R4**	

6. Organization's official website address: www.bccdc.ca (parent organization www.phsa.ca)

7. Name and Title of the person who has legal authority to enter into an agreement and sign on behalf of the organization: **Dr. Mark Tyndall, Executive Medical Director**

8. Project Contact Person *(if different from above)*:

9a. Contact's Mailing Address *(if different from above)*:	9b. Telephone No.: Extension:
	9c. Fax No.:

9d. Contact's E-mail Address: **mark.tyndall@bccdc.ca**

SECTION 2 — Amounts Owing to the Government of Canada

Does the organization owe any monies to the Government of Canada ☐ Yes ☐ No
If yes, complete the following:

Amount Owing	Nature of the Amount Owed (taxes, penalties, overpayments)	Name of Government Department or Agency to which the Amount is Owed
$		
$		
$		

SECTION 3 — Previous Funding

1. Has the organization received funding from the Government of Canada (grants or contributions) within the past 36 months?
   - Yes (provide details below) ☐ No (*If no, go to next section)*

Note: The list below may be used as a reference check.

Name of Department and Funding Program: Public Health Agency of Canada, Vaccine and Immunization Program Surveillance Division	
Contact: Jennifer Pennock	Project Start Date: December 24, 2015
Title: Director, Surveillance and Epidemiology	Project End Date: December 16, 2016
Telephone No.: 613-948-7512	Amount: $ 70,000
E-Mail Address: Jennifer.pennock@hc-sc.gc.ca	Project Title: Solution to transfer BC Adverse Events Following Immunization (AEFI) data to CAEFISS
Name of Department and Funding Program: Public Health Agency of Canada, National Collaborating Centres for Public Health Contribution Program	
Contact: Sarah Bernier	Project Start Date: April 1, 2015
Title: Knowledge Integration & Mobilization Unit	Project End Date: March 31, 2020
Telephone No.: 613-614-1519	Amount: $ 4.868 Million ($973,666/year)
E-Mail Address: sarah.bernier@phac-aspc.gc.ca	Project Title: National Collaborating Centre for Environmental Health
Name of Department and Funding Program: Health Canada, Environmental Health Program, Health Programs & Laboratories, British Columbia Region	
Contact: Meghan Roushorne	Project Start Date: June 4, 2012
Title: Regional Health Risk Assessment and Toxicology	Project End Date: March 31, 2016
Telephone No.: 604-666-8179	Amount: $ 574, 150
E-Mail Address: Meghan.roushorne@hc-sc.gc.ca	Project Title: Linking smoke measurement and prediction to surveillance and response guidelines for the development of a public health approach to forest fires events in Canada.
Name of Department and Funding Program: Health Canada, Environmental Health Program, British Columbia Region	
Contact: Tamara Museau	Project Start Date: 2014
Title: Senior Program Officer, Immunization Programs and Pandemic Preparedness Division	Project End Date: 2018
Telephone No.: 613-867-4186	Amount: $ 855,000

E-Mail Address: Tamara.museau@phac.aspc.gc.ca	Project Title: Influenza-like Illness (ILI) Sentinel Practitioner Surveillance Network (SPSN): Virus and Vaccine Effectiveness Monitoring
Name of Department and Funding Program: Health Canada, Environmental Health Program, British Columbia Region	
Contact: Lisa Landry	Project Start Date: Sept 3, 2013
Title: Assistant Executive Director, Environmental Issues Division	Project End Date: March 31, 2016
Telephone No.: 519-826-2995	Amount: $ 150, 000
E-Mail Address: Lisa.Landry@phac-aspc.gc.ca	Project Title: The Impact of Climate Change on Drinking Water and Health in Vulnerable Water Systems
Name of Department and Funding Program: Health Canada, Health Programs & Laboratories, British Columbia Region	
Contact: Mel Krajden	Project Start Date: 2014
Title: Medical Head, Hepatitis Associate Medical Director, BC Centre for Disease Control Public Health Microbiology	Project End Date: 2017
Telephone No.: 604-707-2421	Amount: $ 135,000
E-Mail Address: Mel.Krajden@bccdc.ca	Project Title: Whole Genome Sequencing Lab Surveillance
Name of Department and Funding Program: Health Canada, Health Programs & Laboratories, British Columbia Region	
Contact: Mel Krajden	Project Start Date: April 1, 2014
Title: Medical Head, Hepatitis Associate Medical Director, BC Centre for Disease Control Public Health Microbiology	Project End Date: March 31, 2016
Telephone No.: 604-707-2421	Amount: $ 178,180
E-Mail Address: Mel.Krajden@bccdc.ca	Project Title: Enhanced Surveillance of Foodborne and Waterborne Diseases in Sentinel Site2: Fraser Health Region, BC: Microbiological Expertise
Name of Department and Funding Program: Health Canada, Environmental Health Program, British Columbia Region	
Contact: Christina Bancej	Project Start Date: Dec 24, 2015
Title: Chief, Vaccine Safety	Project End Date: June 30, 2016

Telephone No.: 613.355.9517	Amount: $ 70,000
E-Mail Address: christina.bancej@phac-aspc.gc.ca	Project Title: Solution to transfer BC adverse events following immunization (AEFI) data to CAEFIS
Name of Department and Funding Program: Health Canada, Environmental Health Program, British Columbia Region	
Contact: Patti Dods	Project Start Date: 2011
Title: Regional Air Quality and Health Specialist	Project End Date: 2016
Telephone No.: (604) 666-9580	Amount: $ 86,000
E-Mail Address: n/a	Project Title: Carbon Monoxide Monitoring Framework in Long-Term Care Facilities and Hospitals
Name of Department and Funding Program: Health Canada, Environmental Health Program, British Columbia Region	
Contact: Douglas Haines	Project Start Date: November 3, 2014
Title: Director, Chemicals Surveillance Bureau Health Canada	Project End Date: September 30, 2016
Telephone No.: (613) 946-7496	Amount: $ 280,000
E-Mail Address: douglas.haines@hc-sc.gc.ca	Project Title: Newcomer Biomarker Project
Name of Department and Funding Program: Health Canada, Environmental Health Program, Health Programs & Laboratories, British Columbia Region	
Contact: Meghan Roushorne	Project Start Date: June 4, 2012
Title: Regional Health Risk Assessment and Toxicology	Project End Date: March 31, 2016
Telephone No.: 604-666-8179	Amount: $ 261,095
E-Mail Address: Meghan.roushorne@hc-sc.gc.ca	Project Title: Linking smoke measurement and prediction to surveillance and response guidelines for the development of a public health approach to forest fire events in Canada
Name of Department and Funding Program: Health Canada, Environmental Health Program, Health Programs & Laboratories, British Columbia Region	
Contact: Ling Liu	Project Start Date: 2015

Title: Head, Air Health Effects Research Section	Project End Date: 2017
Telephone No.: (613) 410-2502	Amount: $ 28,500
E-Mail Address: ling.liu@hc-sc.gc.ca	Project Title: Daily Comm exposure to air pollutant emissions from local industry and the risk of cardiovascular hospitalization
Name of Department and Funding Program: Health Canada, Environmental Health Program, Health Programs & Laboratories, British Columbia Region	
Contact: Nina Dobbin	Project Start Date: 2016
Title: Air Health Science Division	Project End Date: 2018
Telephone No.: (604) 666-2671	Amount: $ 62,500
E-Mail Address: Nina.A.Dobbin@hc-sc.gc.ca	Project Title: Characterizing woodsmoke impacts in BC Communities
Name of Department and Funding Program: Health Canada, Environmental Health Program, Health Programs & Laboratories, British Columbia Region	
Contact: Abderrahmane Yagouti	Project Start Date: January 3, 2017
Title: Senior Analyst, Climate Change and Innovation Bureau	Project End Date: April 28, 2017
Telephone No.: (613) 952-8547	Amount: $ 23,100
E-Mail Address: Abderrahmane.yagouti@hc-sc.gc.ca	Project Title: Building resiliency to extreme heat in BC through the use of health evidence-based information
Name of Department and Funding Program: Health Canada, Environmental Health Program, Health Programs & Laboratories, British Columbia Region	
Contact: Meghan Roushorne	Project Start Date: July 07, 2017
Title: Regional Health Risk Assessment and Toxicology	Project End Date: March 31, 2018
Telephone No.: (604) 666-8179	Amount: $ 95,000
E-Mail Address: Meghan.roushorne@hc-sc.gc.ca	Project Title: Building Greater Public Health Capacity to Address Forest Fire Smoke in Theory and Practice.

SECTION 4	Project Information
1. Project Title: A feasibility pilot for low barrier oral hydromorphone to prevent fatal overdoses	
2a. Planned Project Start Date: **April 1, 2018 (or as soon as funding received)**	2b. Planned Project End Date: **March 31, 2021**

3a. Duration of Project (months): **36**	3b. Total Amount requested: **$1,496,096**

SECTION 5 Capacity and Suitability of Applicant/Lead Organization (up to 1.5 pages)

Please provide an overview of the key roles and responsibilities of your organization for the execution of the project.

Please include a copy of your organization's corporate documents (e.g. Letters Patent, incorporation documents), as a separate attachment(s), as well as a copy of your organization's most recent financial statement, as a separate attachment.

a) Provide an overview of your organization, including your organization's mandate/vision, philosophy/principles and goals. Please also outline how your organization is well-suited to undertake the proposed project (e.g. credibility, relevant skills, interest, and experience with the target population).

The BCCDC provides provincial and national leadership in public health through surveillance, detection, prevention, consultation and provides both direct diagnostic and treatment services to people with diseases of public health significance. Our unique integrated structures, one that combines service delivery, policy advice and research, contributes greatly to the ability to identify and respond to emerging public health threats. This project will be managed under the BCCDC Harm Reduction Program.

The BCCDC has a long history of engaging and partnering with persons who use drugs as the experts in working to reduce substance-related harms. From 2005 – 2010, we sought informal peer engagement via ad-hoc contact with local peer and advocacy groups to inform and contribute to harm reduction initiatives (http://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-016-3136-4).

Evidence-Based Policy and Best Practices Support:
BCCDC provides scientific and best practice guidelines and expertise to communities, non-for-profits and other public sector partners, health authorities, Regional Medical Health Officers, and the Ministry of Health as well as colleagues and organizations leading HR activities across Canada. Examples include best practices for HR supplies provision and distribution; training for front-line staff and clients in safer injection practices; and recommendations for effective communication of drug alerts.

Surveillance and Applied Research
BCCDC uses multiple data sources and methods for surveillance and research of substance-related harms. This work includes strong partnerships reaching into the academic research community as well as harm reduction front-line workers and advocacy organizations within BC and across Canada. At present, the BC Overdose Surveillance Task Group has been struck to ensure timely, consistent and coordinated surveillance reporting to inform and support the provincial and regional responses to BC's opioid-related Public Health Emergency. BCCDC's role is focussed on supporting access to data and improving capacity within the regions to inform local responses. We have formed partnerships and completed data agreements with emergency services, coroners, and drug and poison information centre to fill gaps in our understanding. We use annual surveys through the BC HR sites to obtain more comprehensive information about drug use and related harms across the province. We disseminate our work at national and international conferences, committees, and a wide range of governmental and non-governmental organizations.

Practice Support, Education, and Promotion:
HR practice is supported through the development and dissemination of education and training tools, evidence summaries and recommendations via videos, hands on workshops, social marketing, and communications through a wide network of medical and public health personnel and organizations, government and enforcement stakeholders, and harm reduction and drug user group advocacy organizations.

Nursing excellence:

Since its inception, the BCCDC Nursing Outreach team has provided expertise and provincial leadership in STI/HIV prevention with vulnerable population in outreach settings. The outreach nurses and workers have partnered with a variety of community agencies and stakeholders, using innovative approaches to reach populations often hard to access due to a multitude of reasons. This work has happened in a range of venues from street to clinic to community to the virtual environment. The outreach team has also played a strong role in using the information they have gained through their work to advise and educate. This part of their work has occurred at the individual, community, agency and professional level, with the team being seen as experts in reaching communities that have traditionally been hard to reach and disproportionately affected by STIs, HIV and Hepatitis. The outreach team is expanding to incorporate safe substance use practices into their work. The potential to scale-up and monitor the HM program will potentially require and nursing outreach component and we will have the capacity to use our expertise in this area.

b) Please provide a description of the applicant organization, including governance and capacity to carry-out projects, i.e. staff's work experience, financial administration/management.

The BC Centre for Disease Control and Prevention Society Branch (BCCDC) is a branch society of the Provincial Health Services Authority (PHSA). BCCDC Senior Management consists of an Executive Medical Director and a Chief Operating Officer (COO) who report to the PHSA Vice President, Provincial Population Health, Chronic Conditions & Specialized Populations. The Executive Medical Director and COO have spending authority over the total approved operating and capital budgets for BCCDC.

The Executive Medical Director will oversee the program. The Executive Medical director will be supported by the Manager, Special projects as well as an Operations Manager. Both hold Master's degrees and have over over 5 years of experience in managing public health programs and projects. The Operations Manager currently responsible for budgetary management of several programs and may authorize expenses up to $50,000. Budgets are reviewed on a fiscal period basis.

c) Please provide a brief explanation demonstrating your organization's financial capacity to support a project.

As a result of existing structures within the organization, BCCDC is able to support the operation and delivery of the project through the in-kind contribution of services including: accounts payable and receivable; payroll management and processing; procurement of goods and services; contracts management; technology infrastructure and help desk support; and financial management oversight and human resources services over and above those provided through the program.

As a publicly funded organization, BCCDC, and PHSA must adhere to strict reporting and financial accountability regulations. To this end, BCCDC produces year-end financial statements, overseen by the Board of Directors Audit Committee. Audited financial statements, as well as schedules of remuneration and supplier payments are published on the PHSA's website annually:
http://www.phs.ca/AboutPHSA/PHSA_Budget_Financials/default.htm

Assessment Criteria Section 5

- Applicant is well-suited to undertake the proposed project and is regarded as a credible stakeholder with relevant skills, interest and experience to effectively work with the project's target population(s).
- The proposal demonstrates that the applicant has the required governance, staff work experience, and financial administration/management capacity to successfully undertake the proposed project?
- The proposal demonstrates that the applicant has strong financial capacity to support a project.

SECTION 6 Target Population Group(s) (up to 1.5 pages)

Please provide an outline of the target population group(s) (both primary and secondary audiences) for the project and the geographic locations where you anticipate the program will be implemented.

a) Please provide an outline of the target population group(s) (both primary and secondary audiences) for the project and the geographic locations where you anticipate the program will be implemented (specify national, region, province/territory and municipality).

Target populations:

People at highest risk for opioid overdose based on self-reported and/or documented clinical record of regular illegal opioid use. Key factors to consider include: previous overdose [1], unstable housing [2], and/or private drug use [3]. *Inclusion criteria* includes: regular opioid use/dependency and current consumption of illegal opioids. *Exclusion criteria* include high opioid tolerance (ie. >75mg HM equivalent per day), special populations (eg. youth aged 15 and under) and people who are currently maintained on opioid agonist treatment. The specific inclusion and exclusion criteria will be finalized through further consultation with peers/providers/sites and regulatory partners.

Geographic locations:
Vancouver BC

Settings:
Community partners's overdose prevention sites and supportive housing sites. Staff from each setting will be engaged to help with medication distribution, health service and peer engagement.

b) Describe how the project complies with the **Official Languages Requirements** outlined in **Section 9 of the Guidelines for Applicants**.

This pilot is targeting a single linguistic community as the pilot will take place in predominantly English speaking environments. Specific requests for translation will be accommodated on a case by case basis.

c) Describe how the audiences have been or will be engaged to ensure the intervention is meaningful and relevant to their needs.

The BCCDC works alongside strong organizations of people who use illegal drugs, including the Vancouver Area Network of Drug Users (VANDU), the Canadian Association of People who Use Drugs (CAPUD) and the Society of Living Illicit Drug Users (SOLID) of Victoria (amongst others). Through theirs and others' leadership, we have developed considerable capacity to meaningfully include people with lived experience in policy development, program implementation, and research and evaluation.

The BCCDC recently completed the Peer Engagement and Evaluation Project (PEEP), which has as its aim to enhance peer engagement networks in BC through the development, implementation and evaluation of peer engagement best practices in programs and policies. People who use drugs involved with this project have developed best practice guidelines for harm reduction agencies desiring peer involvement in planning, policy and evaluation work. [4] Members of the PEEP team have represented the concerns of people who use drugs formally, as on the BC Harm Reduction Strategies and Services Committee, and informally, as when consulted on new messaging about emergent overdose messaging. Most recently, the BCCDC used the lessons learned from PEEP to involve people who use drugs in the 2017 Overdose Action Exchange, a full-day solutions-focused meeting which had participation from high-level decision-makers in the BC's Health Authorities, the provincial Ministry of Health, the BC Coroners Service, BC Emergency Response Services, and the College of Physicians and Surgeons of BC, among others. In addition, the findings of PEEP have informed a provincial initiative (Compassion, Inclusion and Engagement initiative) co-led by FNHA and the BCCDC working closely with Regional Health Authorities to facilitate peer engagement, dialogue with service providers and collaborative action to improve the cultural safety, access and relevancy of harm reduction services and programs in communities across BC.

Focus groups have been completed with peers through CAPUD. The results of these focus groups have been used to inform the development of this proposal. We envision continued peer involvement locally, provincially and nationally as we implement, evaluate and expand the project. **A summary of this discussion is attached to the proposal (Appendix 1).**

Meaningful inclusion of people with lived experience is a key principle of this project. To ensure meaningful inclusion, the project team will follow best practices and work alongside organizations of people who use illegal drugs to develop a peer advisory committee. The committee will be involved in informing implementation, evaluation and ongoing management of the project.

The individuals submitting this grant have combined decades of experience in drug use epi demiology,

public health policy and harm reduction, and this proposal is the result of consultation and conversations with peers.

Assessment Criteria Section 6

- Target population groups well-described, including the project's impact on these populations and the geographic locations (i.e. sites) where the project will be implemented.
- Audiences have been or will be engaged to ensure relevance of the intervention to their needs.
- Proposal describes how both linguistic communities will be targeted OR provides a clear justification for why both linguistic communities are not targeted.

SECTION 7 Project Overview (up to 4 pages)

Please provide an overview of the project, including a comprehensive outline of the purpose of the project (objectives/goals), why it is needed, activities, outcomes and how it addresses the identified solicitation priorities. This section should also address how the project complements, ties into, addresses gaps, or builds on other similar initiatives at various levels (e.g. provincial level) or represents an innovative approach to substance use health promotion, prevention, harm reduction or treatment.

Within the scope of your project, consider:

- Does the health issue differ across population groups (e.g., by sex, Aboriginal status, age)?
- Are those differences associated with social, economic, or geographic factors known to affect health (i.e., conditions of disadvantage such as low education levels, socio-economic status, and remote locations)?

If so, consider how your project objectives (a) and outcomes (d) could reduce those differences.

At a minimum, consider the project's expected reach and impact (positive or negative) on the populations disproportionately affected: who is included, who is left out? Note your rationale for these choices. Even if no differences across population groups exist, considering the project's expected reach and impact will help *avoid creating* any such differences. Support your answers in section 6b).

a) Describe the objectives/goals of the project.

The primary objective of this initiative is to reduce overdose deaths in individuals at high risk due to use of illegal opioids from an unregulated and dangerous supply, through providing timely access to a safe opioid supply. Additional goals include to enhance engagement of individuals using illegal opioids with healthcare and social supports; build capacity of service providers and peers to engage in harm reduction and to develop scalable models to replicate and directly involve peer networks in design and implementation. The intended impact of the project is to contribute to drug law reform by demonstrating the benefits of access to a safe, regulated drug supply. Offering low barrier access to a safe supply of oral hydromorphone (HDM) is an essential distribution strategy to reach and engage high risk users who are not currently engaged through conventional harm reduction and treatment services.

b) Provide the evidence-base for the initiative. Building on the LOI, demonstrate and/or expand on the need for the initiative and why it is important to carry out this work.

On April 14, 2016 a public health emergency was declared in BC in response to the epidemic of opioid overdose deaths.[7] Last year, 967 people in BC and 368 people in Alberta died from overdose due to fentanyl contaminating the illegal drug supply, and evidence suggests we are on track to exceed this death toll in 2017.[2,8] Urgent action is required to prevent overdose deaths of individuals most at risk, including males, those who are using alone and who are not connected to health or harm reduction services.[9] Injectable opioid trials have demonstrated strong benefit in reducing morbidity and mortality, as well as drug related harms, and are an important option for individuals with opioid use disorder who do not benefit from current opioid agonist treatment options.[10,11] However, injectable opioid programs are resource and capacity intensive and scale up may be limited, particularly in rural and remote settings across the province where overdose deaths remain high. Thus, offering low barrier access to a safe supply of oral HDM is an essential and complementary distribution strategy to reach and engage users at high risk of harm, particularly those not currently engaged through conventional harm reduction and treatment services. Working within settings designed to increase access for populations that are hidden or marginalized by social and structural inequalities, such as through supportive housing, supervised injection and overdose prevention sites, as well as broader strategies to engage individuals in networks in which they belong, is a critical emergency measure to halt overdose deaths in this unprecedented public health crisis.

The BC Overdose Action Exchange (BCOAE) 2016/2017 reports and Vancouver Police Department 2017 report recommended immediate widespread distribution of effective opioid substitution drugs and increased access to a safer drug supply.[12, 13,] These recommendations address the magnitude of drug deaths associated with the contaminated toxic illegal drug supply, and the public outcry for solutions to the opioid overdose emergency including access a safe drug supply now, before more people die.[14] In the first quarter of 2017, fentanyl was present in 72% of drug overdose deaths in BC,[2] and there were 122 apparent fentanyl related deaths in Alberta.[8] Fentanyl related opioid overdose deaths have been steadily increasing since 2004 in both provinces due to the increasing proportion of street drugs contaminated with fentanyl, which is up to 79% according to a recent study at Insite.[2,15]

A public health harm reduction approach has been well documented to reduce risks associated with injection drug use, including the risk of overdose. Harm reduction initiatives in Vancouver, such as the Insite supervised consumption facility, provide evidence that supervision by trained personnel decreases the risk of overdose death and provides an important avenue to engage in care, learn about using all drugs more safely, and build trust with service providers.[16] The BC overdose response to date has rapidly expanded a number of harm reduction initiatives, including overdose response training for supportive housing facilities, the implementation of overdose prevention sites (OPS) located throughout the Downtown Eastside and rapid expansion of Take Home Naloxone (THN) programs.[17,18] From December 2016 to February 2017, there were more than 20,000 visits to the OPS, over 200 overdoses reversed, and no deaths.[17] However, while the expansion of naloxone distribution has been instrumental in treating overdoses, scaling up naloxone distribution on its own is insufficient to stem the epidemic of overdose deaths as it does not prevent overdoses.[12]

Studies have demonstrated that injectable heroin and hydromorphone (iOAT) is safe and reduces use of street drugs for individuals with severe opioid dependence. Evidence from recent Canadian (NAOMI and SALOME) and European trials demonstrate that people who are long-term, treatment-resistant users of injection heroin do better with a safe and predictable supply of injectable opioid agonist treatment, and the risk of overdose is small.[10,11,19] Based on a similar population, the SALOME trial compared HDM to diacetylmorphine (DAM) determining the overdose relative risk ratio to be 0.28 (0.07-1.17 95% CI), demonstrating that HDM is safe and not inferior. Participants in both studies responded with drastic decreases in overall usage of illegal drugs from daily use to a few days/month.

Although effective, injectable opiate agonist therapy (iAOT) may be challenging to scale up to a level that is needed to address the current crisis. iOAT models of treatment involve intensive screening and appropriate patient selection, structured induction and monitoring, and a high level of support and interaction with staff, requiring considerable resources, capacity and infrastructure to implement.[20] For example, the Crosstown clinic in Vancouver provides iOAT at a cost of $14,000- $25,000 a year per person.[21] The oral HDM pilot applies a public health approach to enable low-barrier access and distribution of safe opioid pills directly to individuals. This provides individuals with a safe alternative to a toxic drug supply until comprehensive drug law reform with a regulated drug supply occurs. Recent evidence from the evaluation of managed alcohol programs (MAP), comparable in that regular, managed dosing of substances is provided to individuals with severe substance use disorders, demonstrates that MAP results in more frequent drinking at lower quantities per day, with significantly fewer alcohol-related health, social, legal and withdrawal related harms for participants.[22]

A community-based focus group with people with lived experience, and key informant interviews with community service providers, provides support for the feasibility, interest in and priority of our alternative model of low barrier access to oral hydromorphone distribution. In Vancouver's Downtown Eastside community, a focus group conducted recently by the Canadian Association of People Who Use Drugs (CAPUD) found overwhelming support for a low barrier access model of oral HDM distribution to prevent overdoses. As one participant affirmed, "any addict who does not want to play Russian Roulette by doing street drugs will so very much appreciate the value of this program." Although practices varied among participants, many said that if given HDM tablets, they would prepare and inject this medication themselves. Participants agreed a graduated approach to daily take-home doses for off-site consumption was appropriate after a trial period, but were willing to initially consume HDM under supervision on site. The vision of this pilot is in line with the formal recommendations and needs brought up by the community, with an aim to increase access to safe opioids.

c) What are the key activities to be undertaken in the project?

We propose a low barrier, scalable model of oral HDM distribution to rapidly expand access to pharmaceutical-grade opioids as an alternative to the toxic drug supply responsible for the epidemic of opioid overdose deaths. Core tenets of the approach include explicit strategies to reach individuals using opioids from an illegal supply, particularly those using alone as well as those not connected to community or engaged with health services; an initial assessment by a physician to assess medical baseline, eligibility for the trial and assess initial dose and titration schedule; follow-up (under delegated authority) by nursing to provide HDM doses, foster trust and build relationships at the service delivery level; ongoing evaluation of the pilot with monitoring for diversion and illegal drug use through regular urine drug screens (UDS); with consideration of a graduated approach from daily witnessed ingestion (DWI) to daily carries based on a history of adherence and continued engagement. Peers have been actively engaged in the design and delivery of the pilot from its inception to ensure accessibility and relevancy to those who are will be using this service.

Key activities for pilot planning and implementation include:

Engaging and consulting stakeholders

We will engage with stakeholders to ensure an adequate feasibility consultation process to address topics such as operational and evaluation protocols for unintended consequences (e.g. diversion) and medication monitoring. Initial consultations have been completed with PHSA ethics (see addendum), legal, as well as a target population focus group. Community partners have been engaged in the planning and are assessing site readiness. Peer networks have been engaged and will be directly involved in pilot design, delivery and evaluation throughout the implementation cycle.

Engagement and consultation with key regulatory bodies regarding how to access and distribute oral HDM has been initiated and will be ongoing over the next 3-6 months (including College of Physicians & Surgeons of BC - CPSBC; College of Pharmacists of BC – CPBC; College of Registered Nurses of BC - CRNBC, Health Canada - HC; BC Ministries of Mental Health and Mental Health & Addictions - MoH, MMHA). In an initial consultation, CPSBC has confirmed minimal regulatory barriers exist as HM is a legal drug that can be prescribed by physicians currently - a list of physicians prescribing for the pilot will be submit to CPSBC in advance of initiation.

Key federal and provincial legislation and regulations governing the distribution, access to and prescribing of controlled substances, inclusive of opioids, include:

- *Controlled Drugs and Substances Act and regulations, include the Narcotic Control Regulation* (federal);
- *Pharmacy Operations and Drug Scheduling Act* (provincial)

Relevant allied health professional regulations and policies in BC include:

- *Safe Prescribing of Drugs with Potential for Misuse/Diversion* (College of Physicians and Surgeons of BC; into effect June 1, 2016)
- *Nurse Practitioner Standards, Limits and Conditions: Opioid Agonist Treatment Prescribing for Opioid Use Disorder* (not yet in effect)

Options for accessing and distributing oral HDM may include sourcing from existing licensed pharmacies; accessing through a centralized pharmacy with a provincial controlled substances distribution role (ie. the government operated Product Distribution Centre that has a pharmacy that supplies opioids to Correctional Services); or seeking approvals for the BCCDC pharmacy for storage and distribution. Whether assessment and HM prescribing can occur under the scope of a nurse practitioner will also be explored (re. Nurse Practitioner OAT Prescribing Standards).

Further feasibility consultations will occur with addictions physicians, health authorities, Medical Health Officers, and Medico-legal/public safety representatives during the first 3-6 months of the project.

Planning and evaluation

Planning activities include:; creating a peer advisory committee, developing policies and procedures (e.g. for unintended consequences), train staff (e.g. overdose management), preparing facilities (e.g. secure medication cabinet, safe injection equipment), initiating evaluation (with community, academic and health partners); planning phased approach to implementation beginning with supportive housing and overdose prevention sites.

Implementation

Phased approach:

- Begin at Lookout supportive housing site to serve 25 people
- Begin at Vancouver Coastal Health overdose prevention site to serve 25 people
- Expand existing sites to serve 50 people each dependent on results of evaluation and partner engagement
- Expand to two more sites (housing and/or OPS) dependent on results of evaluation and partner engagement

- Oral HDM will be prescribed by after an initial assessment by physician through delegated authority to outreach nursing for dosages 'as needed', to a proposed total oral HM dose maximum of 72mg/day (24mg TID) (maximum dosing to be decided upon in further consultation with peers and physicians).
- Medication will be dispensed by a community pharmacist, delivered, documented, audited and stored according to Health Canada and provincial regulations for controlled substances
- Medication will be given to supportive housing residents through existing medication distribution programs and administered by client (within own or designated supervised rooms)
- Initially, consumption will be supervised by staff and/or peers; after initial intake period and evaluation, participants may progress to take-home carries.
- Participants will be offered linkages to health and social services at initial engagement and throughout the pilot through ongoing outreach follow-up (eg. nursing, social workers, housing staff)
- Education regarding use of filters to reduce exposure to fillers (if crushing and injecting) and other harm reduction measures will be provided at initial engagement and throughout follow up
- Urine samples will be collected from participants on a weekly basis using dip sticks to assess for fentanyl, full urine analysis to be completed at baseline and six months for the purposes of evaluation. If an individual is found to have fentanyl in their urine, they will be offered additional health supports; repeated absence of HDM suggest possibility of diversion, resulting in focused educational counselling and health service engagement for continued project participation.

Mitigating Unintended Consequences

Potential unintended consequences will be mitigated and measured by: ensuring all participants meet study criteria for opioid dependence; restricting age limit possibility of youth entering trial who are 'experimental' drug users, with additional clinical evaluation for youth/young adults with opioid dependence to ensure appropriateness for trial inclusion; monitoring urine for the presence of HDM to indicate possible cases of diversion (in these situations, participants will be offered additional education and health supports, and with repeat occurrences, will be asked to leave the pilot); monitoring urine for the presence of fentanyl as an indicator of ongoing illegal drug use (by aggregate as well as longitudinally for individuals, with improving trends/reduced frequency of urine fentanyl contamination interpreted as a positive indicator of safer drug use); educational counselling regarding safe drug use (with an aim to reduce supplementation with illegal opioids and risk of overdose), safe preparation and use of filters if injecting (to reduce risk of exposure to fillers and contamination for those who choose to crush and self-inject pills) and the provision of harm reduction information; ensuring health follow-up by outreach nursing also includes counselling regarding treatment options, such as initiating opioid agonist therapy and that opportunities for OAT referral and initiation are expedited. Additionally, pills will be marked so that they are identifiable in case of diversion.

d) Describe the intended short, medium and long-term results (outcomes) and how this project will positively affect the health of Canadians. In this section, please describe the intended theory of change (i.e. how will the initiative generate an impact towards the SUAP program outcomes).

This initiative will impact change as participants become more stable from a health perspective through the provision of a safer monitored drug supply - this will lead to increased safety, greater health and social services engagement and community connection for individuals who are isolated and at risk, reduce overdose risk and also improve overall well-being.

The primary intended outcome of this initiative is to decrease in overdoses and overdose deaths. Additional key objectives include to reduce use of illegal opioids and increase health and social service engagement. Additional short term outcomes include engagement in learning opportunities with nursing/support staff and changes in knowledge around safe drug use. Medium term outcomes include

rate of soft tissue infections and application of knowledge and skill impacting drug use practices over time. Long term outcomes include patterns of health service utilization, health status, social and housing stability as well as indicators of community connectedness and safety. An ongoing process evaluation will assess improvements in programming and practice, peer engagement in planning and service delivery, local and intersectoral network development and participant satisfaction.

e) Demonstrate the potential of your project to have national applicability. Building on the LOI, please describe how the project could be transferred to different settings or target populations; or expanded into other parts of Canada (e.g. how project partners can help expand the reach of the project).

Provinces across Canada are experiencing an alarming increase in overdose deaths. The Minister's Opioid Emergency Response Commission in Alberta was created in May 2017 to address opioid overdose deaths. Recently, other provinces (such as Ontario) have fielded calls for the declaration of a public health emergency (CBC, Aug. 28, 2017). The project lead is Dr. Mark Tyndall, who is Deputy Provincial Health Officer for the province of BC, in partnership with Dr. Karen Grimsrud, Chief Medical Officer of Health for Alberta who will collectively provide leadership at the national level in disseminating and advocating for uptake of the results of the pilot.

f) Provide an overview of the project's alignment with the SUAP's priority areas, as outlined in the Guidelines for Applicants

This project aligns with the focus on supporting innovative responses to Canada's opioid crisis across the harm reduction and prevention continuum. In particular, this project will support the priority of expanding access to and overcoming barriers to innovative harm reduction models, with a focus on peer engagement; in addition to engaging with and building community capacity and promoting the benefits of harm reduction for individuals with drug use that may be higher risk (ie. those using opioids from an illegal supply, using alone). This initiative will also support capacity development for service providers to build knowledge, skills and tools to support better harm reduction practice, as well as generating data to help inform the opioid response activities.

g) Choose and describe the question which best applies to your project:

While significant focus has been placed on the contribution of opioid over-prescribing by the medical community in fuelling the current population level of opioid dependency, the current overdose crisis is a direct consequence of the prohibition of drugs and a lack of regulation and consumer protections that has allowed black market capitalism to produce increasingly toxic products. A public health response must ultimately draw on our discipline's experience in consumer product safety to regulate a legal market. Until this occurs, the urgent need to make safer opioids available to those at risk of overdose can be accomplished through public health prescribing.

Public health prescribing can ensure essential medication is available when needed. In communities across Canada affected by the opioid overdose epidemic, naloxone is currently available by prescription from physicians and nurses, or through a medical directive from a physician.[17] Due to the rapid increased demand, medical directives became a popular means to rapidly distribute this life saving medication and provide opioid overdose response training.[17] In this public health prescribing approach, the physician's medical directive delegates the delivery of naloxone to another person (e.g. nurse, counselor, or other frontline staff) who "possess 'the appropriate knowledge, skills and judgment' to carry out the action" of delivering naloxone to a person in need.[17] The physician is still ultimately responsible for his/her medical directive, and therefore must ensure those who they are delegating receive proper training, that the medication is safety stored and handled, and that quality review of these processes occurs.[17] If we apply the same principles of public health prescribing using medical directives, oral HDM could be considered an "essential" drug to prevent overdoses in the context of a contaminated drug market.

Public health prescribing is complementary to but differs from an addiction medicine model, which effectively treats addiction but is not able to reach all individuals at risk at a population level. Ultimately, there are many more people at risk of opioid overdose death than would qualify or have access to such an intervention. Public health prescribing employs a general distribution process to rapidly increase access a safe drug supply in the community, and utilizing this model in our low barrier access to oral HDM pilot provides many potential advantages to the addictions medicine treatment currently available. First, oral hydromorphone is inexpensive ($0.32/8mg dose) compared to iOAT, therefore its use will allow rapid scale-up to reach many people at risk of overdose. Second, low barrier access means people who are using alone can benefit by potentially allowing them take-home doses

and the choice of where to use. This is vital because over half of overdose deaths occur in private residences, and roughly 40% of overdose deaths occur when people use alone,[7] and the autonomy provided by our model will likely lead to greater uptake by these individuals. Third, a low barrier access model would reach people who are not able to adhere to observed therapy multiple times daily, and if the initial pilot is successful, may not require physician expertise. Therefore, we could more easily apply our model to other locations where existing infrastructure and human resources for iOAT do not currently exist. This is important because communities in all five health regions in BC have overdose mortality rates greater than 15 per 100,000 population but they are not currently equipped to provide intensive iOAT treatment.[7] Finally, as a harm reduction point of care, this pilot could foster greater engagement in the healthcare system through potential referrals. This is not out of keeping with current initiatives to develop a more accessible addiction treatment model, however as this unfolds we must also take a public health approach for an emergency response to address the current crisis

Assessment Criteria Section 7

- To what extent are project goals/objectives clear, realistic and achievable?
- To what extent is the need for the project supported by evidence that is well-documented (including research evidence/statistics on the target populations and issue being addressed; previous project evaluations as applicable; and a theoretical basis for the project) and includes a strong rationale for the importance of carrying out this work?
- Project activities are clear and well-aligned with the objectives of the project and the priorities of the solicitation.
- To what extent are expected short term, medium term and long term project results (outcomes) well-described, including how the proposed project will positively impact SUAP program outcomes.
- To what extent does the proposal demonstrate national applicability by describing how the project could be transferred to different settings or target populations or be expanded into other parts of Canada?
- To what extent does the project overview align with the priorities of this invitation as outlined in the Guidelines for Applicants?
- To what extent does the proposal describe how the project will complement or build on other similar initiatives or describe how the project represents an innovative or new approach to substance use health promotion, prevention, harm reduction or treatment (based on which best applies to the project)?

SECTION 8 Partnership(s) and Collaboration (up to 2 pages)

Projects should include multi-sectoral or multi-agency partnerships.

Please include signed official letter(s) (as an attachment(s)) from all external organization(s) involved in the project demonstrating their collaborative commitment and their contributions to the proposed project (financial or otherwise).

a) In the table below, indicate the names of the partners you will work with during the project (including any new partners that have been confirmed since the LOI stage) and describe their role and contribution.

Name of Partner Organization	Partner's Role	Partner's Contribution (Financial/In-Kind)
Lookout Society	Lookout will provide housing and clinical space in multiple locations and medication administration teams for the pilot, and engage residents in the peer advisory network and for peer employment.	Space/room in- kind leasing cost of $500 a month ($6000 per year)
City of Vancouver	Providing $58,930 in project funding from its 2017 Contingency Budget for the Opioid Crisis	$58,930 in project funding total
Vancouver Coastal Health Authority (VCH)	VCH will provide in-kind rent at several existing overdose	In-kind rent total: $100,000 per year, shared staffing/and peer

	prevention sites and existing clinical spaces as well as crucial access to their system of substance use, primary care and mental health services for referrals.	honorarium resources where feasible: up to $100,000 over 3 years
Canadian Association of People who Use Drugs (CAPUD	CAPUD will provide peer leadership, peer employment and advocacy in the project and will lead the peer evaluation component. Will also be involved in peer advisory and peer employment opportunities.	Advisory support
BC Observatory for Population and Public Health (BCOPPH)	Provide collaborative leadership in the development of provincial and regional surveillance capacity for non-communicable diseases, including mental health and substance use.	Part of BCCDC
BC Center for Substance Use (BCCSU)	A range of supports associated with the evaluation component of this project, including qualitative and quantitative assessments of patient access and outcomes using program of ethno-epidemiology and cohort-based research.	Advisory and evaluation support
MInistry of Mental Health and Addictions	The BC Ministry of Mental Health and Addictions will contribute to the project by actively participating in its planning, implementation and evaluation.	Advisory support
UBC School of Population and Public Health (SPPH	Lead investigators from the NAOMI and Salome clinical trials will providence evaluation guidance and share lessons learned from the implementation of injectable heroin and hydromorphone trials with the BCCDC team.	Assuming two weeks per year at various salary levels yields an estimate for in-kind support of $10,000 per year.
Canadian Drug Policy Coalition	Partner with the BCCDC and bring a strong network of experts at the community and academic level to support this project.	In-kind time (approx. 2 days/month) $18, 000 per year
The Minister's Opioid Emergency Response Commission, Alberta	Commit to collaborate with the models in Vancouver to complete some pilot studies in Alberta. Sit on advisory committee.	The in-kind contribution would be 1-2 days per month by either Elaine or Kristen to work on an advisory-type committee. (letter of support to be sent Mon Oct 23, 2017)
b) Indicate the anticipated benefits of working with multi-sectoral or multi-agency partners and how it will impact your project as well as substance use health promotion, prevention, harm reduction or treatment more broadly.		

The BC Centre for Disease Control will leverage the partnerships outlined in this proposal and other relationships with public health organizations at the local, provincial, and national level (both community and government) to inform our project and expand to other areas to improve harm reduction and treatment measures more broadly.

We will share resources between agencies to contribute to a coordinated public health response to illegal drug harms. We hope that this project will strengthen relationships and facilitate increased information sharing relating to the overdose crisis.

Assessment Criteria Section 8

- The project demonstrates multi-sectoral or multi-agency engagement or involvement with organizations from various sectors and includes a list of all project partners.
- The role and contribution of each partner clearly described and confirmed by letter of support.
- The proposal describes how working within a multi-sectoral or multi-agency partnership will result in a positive impact on the project and on health promotion, prevention, harm reduction or treatment more broadly.

SECTION 9 Sustainability / Ongoing Impact (up to 1 page)

Time-limited project funding cannot be used to sustain the operation of organizations or to carry out ongoing core operational activities that must cease when funding ends. Therefore, sustainability should be considered as a process, rather than a phase, and must be embedded within the design and implementation of the project. Sustainability should be linked to your knowledge translation and exchange goals and activities for your project or initiative as well as your performance measurement and evaluation strategy. Sustainability can include:

- Maintenance or ongoing impact of project outcomes
- Maintenance or ongoing impact of partnerships
- Continuation of project activities
- Integration of what has been developed or learned at the organizational and/or systems level

a) Please provide a description of how sustainability has been embedded within the design and implementation of the project, including how it is linked to your knowledge translation and exchange activities and any role your partners will play in supporting project sustainability.

The knowledge translation materials (one page guide, program resource guide and BCCDC expertise (nursing educators) can be used to support implementation of low barrier oral HDM program anywhere that funding exists. The KT materials will be designed so that they are easy to use and can be transferred to any location in Canada. Project partners will be involved in the design, dissemination and implementation (where applicable) of the project and its KT materials.

b) What aspects of the project do you envision to be sustained after funding has ended? What barriers to sustainability or enablers for sustainability can you identify?

If evaluation shows that this pilot is successful in reaching project objectives, KT materials can be transferred to other interested sites and locations across Canada. Ongoing funding will be required for staffing and medication costs. However, the project uses existing capital as well as staffing resources and knowledge. Staffing and medication costs can be embedded into ongoing programming at existing sites so that sustainability is not dependent on one time federal funding. Upfront costs (such as storage and initial training and setup) can be sustained at any site that acquires them. A detailed sustainability plan will be developed to ensure programming is continued at the completion of federal funding.

Assessment Criteria Section 9

- The proposal outlines the sustainability process embedded within the design and implementation of the project; identifies potential sustainable elements; accounts for barriers and enablers; and, describes the possible role project partners might play in supporting project sustainability.

SECTION 10 Knowledge Translation (up to 2 pages)
Knowledge Translation (KT) activities "move knowledge to action to ultimately improve the health of Canadians." A knowledge translation activity is more than disseminating a product or final report. It is an active process that includes the synthesis, dissemination, exchange and application of knowledge to ultimately improve the health of Canadians. It involves purposeful interactions among people who produce knowledge and those who use knowledge. How knowledge is shared depends on the context in which interactions take place; the needs, roles, resources and capacity of knowledge producers and users; and the knowledge type and findings. Projects must demonstrate the use and translation of information and knowledge by applying the '**knowledge to action model**' detailed in **Section 11 of the Guidelines for Applicants** to ensure that not only appropriate knowledge is generated but that it is also put into action. Based on the knowledge to action model:
a) What knowledge products/activities will be developed or conducted as part of this project? Have any new knowledge products/activities been identified as part of your project plans since the LOI stage? Be specific about what knowledge/knowledge products will be developed and why they are needed. Knowledge translation products will include a one pager description of the rationale and details of the pilot that will be disseminated to peers and service providers to solicit interest and provide more information on the project. On-site service providers will be trained to conduct a short educational session with participants on pilot enrollment (re. drugs and drug classifications, safe drug use practices and overdose risks/prevention). Centralized outreach nursing capacity at BCCDC will provide in house educational expertise and support to partners involved community level implementation, including assisting with pilot adaptation to local contexts. This will also include the development of an introductory program implementation guide that will evolve with feedback and learning over the course of the pilot. Academic publications will be produced to inform academic, health provider and policy makers.
b) Who are your key target audiences for each knowledge product/activity? The key target audience for the one pager description will include peers who will be enrolling in the project and contributing as peer advisory board members. A separate one pager description will be provided to community service providers (which may include nursing staff, supportive housing staff, social workers and other staff involved in follow-up and pilot administration) with project background and details about the pilot protocols/process. Centralized outreach team staff will provide supports for project implementation to ensure consistency and help trouble shoot issues. Process evaluation results will be used to inform the development of a program implementation guide which will be distributed to other jurisdictions/organizations interested in replicating or scaling up their own initiative.
c) How will your target audience(s) become aware of and access your knowledge products/activities (i.e. what are your dissemination strategies) and how are partners and stakeholders involved? Knowledge products providing information on the initiative will be disseminated through existing BCCDC, partner and peer networks to inform recruitment and engagement. Knowledge brokers, including peers, will be engaged to help introduce and disseminate information on the project. Project updates (published after one year of the pilot) and the final program implementation guide will be disseminated through professional networks within health and supportive housing sector, published online at the BCCDC/Towards the Heart website (http://towardtheheart.com) and partner websites (such as http://canadianharmreduction.com). Academic dissemination mechanisms in peer reviewed journals and conferences will be considered.
d) How do you plan to follow-up with your target audience(s) to monitor and evaluate the uptake and use of the knowledge and its impact on policies, programs, behaviours or practices? Be specific about what you will do with the knowledge/knowledge products you create or use and the steps you will take to move beyond dissemination to implementation/uptake (i.e., how the knowledge will be applied).

We will follow up with project participants to assess connection to care (self-report and linked administrative data), drug use patterns (self-reported), health status (e.g. reduction in overdose events). We will connect with community site providers to assess their level of satisfaction with program implementation and recommendations for improvements. Upon completion and posting of the program implementation guide, we will serve as an implementation resource for other organizations/jurisdictions who are initiating their own oral HDM programs.

Assessment Criteria Section 10

- Knowledge products/activities to be conducted clearly described?
- Target audiences for each knowledge product/activity clearly identified?
- The proposal indicates how knowledge products/activities will reach the project's target audiences, including how they are being disseminated and who is involved?
- The proposal indicates how the project will follow-up with target audiences to monitor the uptake and use of knowledge and its impact?

SECTION 11 Sex- and Gender-Based Analysis (up to 1 page)

Please explain how Sex and Gender Based Analysis (SGBA) efforts have been integrated into the proposed intervention, including information on justification, links to evidence, interactions with other relevant determinants/variables, evidence of reference to resource documents on SGBA, description of intents related to analysis, reporting and evaluation.

a) How has SGBA been integrated into the proposed intervention?

This pilot will integrate sex and gender based analysis (SGBA) into the intervention and evaluation by partnering and consulting with a variety of community based agencies who provide tailored services and safe consumption spaces for women only and work with these organizations for the SBGA component of the evaluation. We will also address the fact that 80% of overdose deaths occurred among men, many of whom had used substances alone 7. The low barrier program will help to overcome the social and psychological barriers men experience to accessing services, and the peer-based environment will help build supportive relationships that men might have difficulty building in other environments.

Factors related to biological sex including determining appropriate dosing (namely body size) will be monitored through physician and nurse assessment and consultation. This will be completed in a gender sensitive way considering individual differences on the continuum of sex.

b) How does the proposed intervention respond to the continuum of gender considerations in programs and policies detailed in **Section 10 of the Guidelines for Applicants**?

Our intervention is gender sensitive It acknowledges the impact of different gender norms, roles and relations. We are intentionally targeting men using alone who represent 80% of over dose deaths. However, we will also be sensitive to the needs of women, trans and non-binary folks by ensuring that we provide safe space for them to access this intervention. Our intervention is also gender specific in that it aims to provide a safe supply of drugs for folks (primarily women, trans and non-binary folks) who may experience violence when accessing the street drug supply from dealers or other community members.

We will develop gender specific and implementation strategies to ensure that we are reaching the men who are using alone and so that we are sensitive to the needs of women, trans and non-binary folks.

c) How will data collected through the proposed intervention enable health equity analysis by examining impact on sex and gender?

Survey data will include the collection of information relating for gender identity(woman, man, non-binary, other (i.e. trans)) (yes/no/prefer not to say) alongside questions about safety and community engagement. This will allow us to ascertain who the intervention is reaching and understand if our services are gender appropriate. These results will enable us to evaluate how we deliver services and

change to ensure gender specific needs are met.

Assessment Criteria Section 11

- SGBA efforts have been integrated into the proposed intervention, including information on justification, links to evidence, interactions with other relevant determinants/variables, evidence of reference to resource documents on SGBA, description of intents related to analysis, reporti ng and evaluation.
- The proposal responds to the continuum of gender considerations in programs and policies.
- Data from the project enables analysis of impact on sex and gender.

SECTION 12 Work Plan and Timetable

Complete the SUAP Work Plan template (ATTACHMENT #1), inserting additional rows as necessary, and attach separately.

a) Please complete the Work Plan and Timetable template and attach separately.

Assessment Criteria Section 12

The completed Work Plan identifies the following:

- Well-defined activities that will achieve project objectives;
- Feasible timelines that reflect the requirements of the activities being proposed; and
- Appropriate outputs that reflect the project activities being proposed.

SECTION 13 Performance Measurement and Evaluation

1 page for the written description below; a project Performance Measurement and Evaluation Table (ATTACHMENT #2) to be attached separately

a) Please provide a brief written explanation of the performance measurement and evaluation methodology and activities for your project.

Key aspects of the evaluation plan will be determined with participatory input from peer advisory group and service providers engaged in the project. A mixed methods quantitative and qualitative evaluation approach will be used to assess the impact of the intervention on overdose risk among the participants. Additional outcomes may include engagement in care and treatment, rates of soft tissue infections, social and housing stability, patient satisfaction, as well as indicators of community connectedness and safety. A process evaluation will reflect the project's participatory approach to assess participant's satisfaction with program delivery; changes in collaboration and connection across health and social sectors; peer engagement and leadership; as well as important factors contributing to the success of project implementation to inform future scale up and application to diverse settings across BC. The pilot will include an evaluation of any potential negative harms (e.g. escalating use) of using HDM off-label.

This pilot is designed, in keeping with public health principles, as a community level approach. The evaluation should keep this in mind, particularly regarding diversion of drugs: an individual-focused evaluation model would view this as a failure, where a community-level assessment might find that diversion to others at risk of overdose produces a net benefit in community safety. The pilot has engaged partners in community settings with existing research infrastructure in the communities where the intervention will be piloted. Although, it should be noted that many people who use drugs are currently crushing and injecting tablets of unknown purity and this pilot will offer a supervised injection setting with the opportunity to provide harm reduction supplies and education around filtering and cooking to remove impurities while providing a safe, untainted supply of opioids.

All individuals participating in the program will be invited to enroll in a prospective cohort study to longitudinally assess the impact of program participation on a range of outcomes. Participants will complete baseline surveys exploring drug use history (including amount and type of drugs used, current method of administration, source of prescribed and illegal drugs, locations of use and whether using alone, age at first use and trajectory of drug use); history of prior adverse events (e.g. # overdoses, # reversals, last overdose etc.); social history (housing status and duration, employment etc.); as well as history of legal, employment, drug dealing and sex work involvement. Follow-up surveys conducted 1 month later and at 6 months will provide data regarding ongoing illegal drug use; key health outcomes

and adverse events, including overdoses and health service utilization; indicators of personal resiliency and social stability, including engagement in treatment, legal and sex work involvement; as well as connection to community. Program records will provide data on program access and hydromorphone use (frequency, dosing, trends over time). At the pilot onset, participants will be asked to provide consent for health data to be analyzed from linked administrative databases (e.g. hospital discharge records, physician billing, pharmanet, Vital Statistics) - for individuals with a provincial Personal Health Number (PHN) - to allow assessment of health outcomes (e.g. overdose), history of prescribed medications and service utilization including hospitalization, emergency visits and physician visits. For the purposes of analysis, participants will be stratified based on access to/use of the program (i.e. duration/frequency of program involvement).

Participation in educational and training sessions regarding drug and drug classifications, substance use disorders, overdose risks and prevention as well as harm reduction will be tracked through program data, with participant surveys at baseline and follow-up providing self-reported data on changes in knowledge and skills as a result of the training, as well as knowledge and skill application impacting behavior change over time. Where available, community setting data (i.e. supportive housing data repositories with baseline data) will provide information regarding changes in service access, trends of key indicators (i.e. # overdoses, # overdose reversals etc.), as well as indicators of social stability (e.g. duration of housing stay) and community safety (e.g. presence of discarded drug equipment, # of violent incidents).

As well, ethno-epidemiological approaches used previously by the study team will be employed to assess a range of processes and outcomes in more depth. Specifically, subsets of participants will be recruited for participation in qualitative interviews focused on their experience with the program. This ethno-epidemiological aspect of the evaluation approach has been peer-reviewed, funded by the US National Institutes of Drug Abuse (PI: McNeil), and approved by the UBC/Providence Health Care Research Ethics Board.

Key informant interviews will be conducted with core stakeholders, partners and peer leaders at implementation and bi-annual intervals to capture lessons learned and important factors contributing to success of project implementation, education and training; as well as improvements impacting substance use policies, programs and practice by staff and leadership through sharing of processes, educational resources and tools.

Comparison with the Vancouver Injection Drug Users Study (VIDUS) will be used to assess potential diversion or increases in illegal use of diverted HDM, as well as potential positive consequences, since VIDUS will offer data on those exposed and those not exposed to the program. In addition, comparison with the VIDUS cohort could help characterize individuals who initiate the program versus those that don't to identify factors associated with participation, to help determine whether the target population is being reached.
Cost savings from averting high intensity service utilization, (i.e. hospitalizations, emergency room visits), will be estimated using administrative data from pre-post pilot periods for all clients and a future cost effective analysis.

b) Identify how research ethics considerations will be addressed, including informed consent, confidentiality, and participant safety. If any collaborators are affiliated academic institutions, please identify any corresponding Research Ethics Board approval requirements.

Under development pending further discussion with academic partners.

c) Complete the Performance Measurement and Evaluation Plan Table (template attached) for your intervention.

Assessment Criteria Section 13
The proposal includes an overview of the intervention's performance measurement and evaluation activities to be conducted, including a clear description of:
- Elements to be measured and evaluated (e.g. outputs, reach, outcomes);
- Data collection methods (e.g. surveys, web metrics);
- Source of information (e.g. project participants, program staff);

- Intended measurable results that indicate changes related to SUAP program outcomes; and
- Any research ethics considerations and appropriate measures to address them.

The proposal includes a Performance Measurement and Evaluation Table with outcomes that are aligned with the SUAP Logic Model outcomes, and appropriate indicators and data collection methods.

SECTION 14 Detailed Budget and Budget Narrative
Complete the SUAP budget template and narrative justification form (ATTACHMENT #3) and attach separately to provide details of all activities and associated costs for each year. **Notes:** • **All costs must be directly related to the project.** • **Space or equipment owned by the organization should be identified as an in-kind (non-financial contribution.** • **The federal government's fiscal year begins April 1 and ends March 31.**
a) Please complete the Budget and narrative justification form and attach separately.
b) Please outline other sources of funding / partner contributions (financial).

Assessment Criteria Section 14

- The total funding requested from Health Canada (total budget) is appropriate to support the proposed activities and demonstrate value for money and ability to leverage multi-sectoral or multi-agency financial and in-kind contributions.
- The budget narrative descriptions provided are appropriate and clear to assess/support the amount requested in each budget category.

SECTION 15 Approval

The undersigned on behalf of the organization declares that:

- The information in this application and all accompanying documents are accurate and complete;
- No current or former public servant for whom the *Health Canada Values and Ethics Code*, the *Values and Ethics Code for the Public Sector*, the Treasury Board Secretariat *Policy on Conflict of Interest and Post-Employment* and the *Conflict of Interest and Post-Employment Code for Public Office Holders* applies, shall derive any direct benefit from this funding request including any employment, payment or gifts, unless the provision and receipt of such benefits is in compliance with such codes and policy; and
- The funding request is made on behalf of the organization named in Section 1 with its full knowledge and consent.

I acknowledge that should this funding request be approved, funding will be conditional upon the organization signing a written agreement with Health Canada.

Authorized Representative of the Organization

1.

Name: Dr. Mark Tyndall
Title: Executive Medical Director
Telephone Number:
Fax Number:
E-Mail Address: mark.tyndall@bccdc.ca
Signature of Authorized Representative:
Date: October 20, 2017

☐ Mark Tyndall

2.

Name:
Title:
Telephone Number:
Fax Number:
E-Mail Address:
Signature of Authorized Representative:
Date:

☐

MUST BE SIGNED BY INDIVIDUAL(S) AUTHORIZED TO LEGALLY BIND THE ORGANIZATION

DETAILED BUDGET & NARRATIVE JUSTIFICATION FORM

Please complete and attach the Excel-based SUAP **Detailed Budget Template** provided with your invitation to submit a proposal. There are three tabs within the template:

- An Expenditure-based Budget sheet
- An Activity-Based Budget sheet
- A description of the budget categories

Please complete **both** the Expenditure and Activity-Based budget templates and attach to your proposal submission.

Please also complete the **Budget Narrative Justification Form** (below) as part of the full proposal document submission.

BUDGET NARRATIVE JUSTIFICATION FORM

BUDGET ITEMS

Personnel

Full time employees: (*position titles, role in the project, salary before deductions)*
n/a

Part time employees: *(position titles, role in the project, number of hours worked per week, hourly rates)*
Note: Health Canada only refunds time worked on the funded project. Health Canada does not pay for vacation and sick leave of part-time employees.

Project coordination BCCDC .8 first year, then .5TE each year
Provides administrative assistance and coordination to sites and facilitates organization of peer advisory committee and other stakeholder engagement. Also organizes for KT and evaluation to occur.
Year 1: $44,000
Year 2: $22,000
Year 3: $22,000

Project management BCCDC .8 first 6 months, then .2 FTE each year
Provides oversight to project management ensures effective project roll out and ongoing success, assist with ongoing reporting, attend peer advisory meetings, manage overall project budget.
Year 1: $56,000
Year 2: $16,000
Year 3: $16,000

Project nurses 2 days per week per site 6 months year 1, year 2 and 3 ($280 per day):
Provide nursing support/connection to care to individuals enrolled in pilot, will provide medications, report adverse outcomes etc. may be employed by each individual site. Intended as top up to existing staffing.
Year 1: $58,240
Year 2: $116,480
Year 3: $116,480

Front line health and/or support staff (i.e. social worker equivalent (.5FTE per site) 6 months year 1, year 2 and 3:
Will provide follow up, complete surveys, connect to care. May be employed by each individual site or overall., reporting adverse outcomes etc.
Year 1: $45,760
Year 2: $91,520
Year 3: $91,520

Peer workers .25 FTE equivalent per site $15 per hour
Will provide follow up, complete surveys, connect to care and other supports.
Year 1: $31,200
Year 2: $31,200
Year 3: $31,200

Benefits: *Breakdown (employer's share of QPP, CPP, EI, Worker's Compensation Board, 2 weeks holidays per annum for full-time employees, federal and provincial holidays)*

Year 1: $19,536
Year 2: $22,814
Year 3: $22,814

CPP @ 4.95%
EI @ 1.63%
WCB BC @ 1.65%

Goods & Services - Contractors

Contractors: (*role in the project, number of hours worked per week, hourly rate)*

Public health physician 8 sessions per month at $440 per session = **$42,240 per year**

Travel - Details apply for each meeting
Transportation: *(purpose of travel, economy airfare, taxi, automobile, bus, train; provide details regarding who will travel and for what purposes)* n/a
Accommodation: *(number of nights, number of participants, hotel rates)* n/a
Meals and Incidentals: *(number of meals, number of days; not to exceed Treasury Board Travel rates)* n/a
Goods & Services – Meetings / Events
Room/Space Rental: Focus groups to be completed at BCCDC or at community organizations in-kind.
Hospitality: *(not to exceed Treasury Board rates)* A catered lunch will be provided peer advisory meeting (4 per year). The approximate number of for each focus group 20. This includes project staff and peer advisors. Cost: $361 per meeting ($18.05 – standard lunch cost as per NJC x 20 people) **$1,444 per year**
Services: *(translation, etc.)* n/a
Materials
Office Supplies: *(stationery, pens, envelopes, reference manuals)*
Project Materials: (*purpose, type, and cost of materials, website licence fees (if part of the overall project), cost of subscriptions for items required for the project)* Hydromorphone: Year1: 50 participants for 6 months: **$34,770** Year 2: 100 participants for 12 months: **$138,700** Year 3: 100 participants for 12 months: **$138,700**
Printing/Photocopying: *(purpose, type, price)* Printing and photocopying one page survey per 100 participants per week for three years at 10c. per page **$520 per year** (cost estimate at 100 each year to account for misc printing or photocopying expenses)
Postage: *(regular, messenger services, courier)*
Other (specify):
Equipment
Office Equipment: (*purpose, type and price; e.g., cost of renting or purchasing computers, calculators, maintenance, if owned by the recipient)* In-kind provided by BCCDC and partnering sites
Furniture: (*only in **exceptional** circumstances should furniture be purchased. Furniture used for the project should be provided by the recipient as an in-kind contribution.)* In-kind provided by BCCDC and partnering sites
Special Equipment: *(purchase or rental is on a case-by-case basis; the equipment must be unique and necessary to carry out the project and rented as opposed to purchased.)* Medication administration desks, locked storage for controlled substances, stainless steel tables for supervised injection, sturdy, chairs, mirrors $10,000 per setup. **$20,000 year one** for two sites, **$20,000 for**

two new sites (year 2)

Rent/Utilities

Rent: *(rent is based on square footage used for the project – indicate how the portion to be charged to this project was calculated.)*

Provided in-kind by BCCDC and participating sites

Utilities: *(phone, hydro, heating; indicate how the charge is prorated to this project)*

Provided in-kind by BCCDC and participating sites

Knowledge Translation and Dissemination

Dissemination: *(what, where, how, cost)*

One page guide disseminated at beginning of project and as new sites are established.
One page guide will be available online (BCCDC website) and in print). For example; will be distributed through email lists, in person at specific events (e.g. conferences), and posting on social media sites.

Knowledge translator will be contracted to design one page guide: **$500 (year 1)**

Final program implementation guide will be available after the completion published online to be provided after year one evaluation.

Knowledge translator will be contracted to design final implementation guide: **$1500 (year 2)**

Materials to be distributed by mail as requested: it is estimated that we will send 50 documents nationally throughout the project @ $6 per report =**$300 ($100 per year)**

Performance Measurement & Evaluation

Evaluation: *(cost of external evaluation, analysis, cost breakdown of evaluation components)*

Process evaluation - external evaluator.
Project to be evaluated after 6 months **($5000)** then at end of year one **($2500)**, two **($2500)**and three **($5000)**. Printing of evaluation resources **$500 per year**.

Other (specify)

Other: *(e.g., translation/interpretation - specify purpose, description, rate or prorated charge)*

Note: Items included under this "other" category should be kept at a minimum.

Urine toxicology *including transportation of specimens and reporting of results* (work with BCCDC toxicology lab)
$65 for tested specimen baseline (full screen) (every participant at entry)
$65 for tested specimen 6 months (full screen) (every participant at 6 months)
Weekly dipsticks $3 per person per week

Year1: 50 participants for 6 months (1 x per week at start of program then one month thereafter) = **$10,400**
Year 2: 100 participants for 12 months (1 x per week at start of program then one month thereafter) = **$28,600**
Year 3: 100 participants for 12 months (1 x per week at start of program then one month thereafter)= **$28,600**

Accounted for 50, 100, and 100 as entrants in years 1, 2, and 3 respectively to capture new entrants / participants exiting the pilot and additional screening/wastage that may be required.

Peer honorariums. $20 per hour x 15 peers x 4 ½ day meetings per year. **$3600 per year**

Other Sources – Financial

Are the activities under this project funded through funds/monies from other funding sources?
If yes, specify name of funder(s) and status of contribution(s) (approved or pending – indicate contingency plan should funding not be available).

City of Vancouver $58,930. If not available we will seek to find funds from another funder.

Other Sources – Non-Financial (In-Kind)

In-kind contributions are goods or services provided to the project, sometimes by the recipient organization itself, for which no exchange of money takes place. Examples include the use of office space, equipment, materials, supplies, and services provided by professionals on a voluntary basis. Donations of money are categorized as "other sources of funding" and not as an in-kind contribution.

Are in-kind contributions being made by **your** organization for the activities of this project?

In kind epidemiologist (1/10 time) per year: $9,000
In-kind executive medical director time (1/10 time) per year $17,500
In-kind chief operating officer time (1/10 time) per year: $15,000
In-kind other expert staffing time (2/10 time per year): $30,000
In-kind administration staffing time (1/10 time per year): $5,000
In-kind meeting space: $800 per year
In-kind syringes: $9.38 per 100 unit (at least 100 per day): year 1: $1711, year 2 & 3: $3,424
In-kind filters: $255 per 1000 unit (at least 100 per day): year 1: $4,654, year 2 & 3: $4,654

Total per year1: $83,665 year 2 & 3: $90,032

Are in-kind contributions being made by **other** organizations for the activities of this project?

Lookout Society: Space/room in- kind leasing cost of $500 a month **($6000 per year)** (confirmed in letter of support)

Vancouver Coastal Health Authority (VCH): in kind rent costs/ shared staffing/ and peer honorarium costs up to **$33,333 per year** confirmed in letter of support

UBC School of Population and Public Health: Assuming two weeks per year at various salary levels yields an estimate for in- kind support of **$10,000 per year.** confirmed in letter of support

Canadian Drug Policy Coalition: in-kind time (approx. 2 days/month) **$18, 000 per year** confirmed in letter of support

The Minister's Opioid Emergency Response Commission, Alberta: The in-kind contribution would be 1-2 days per month **$XXX per year to be** confirmed in letter of support (expected Monday October 23, 2017.

Total per year: $49,333

TOTAL: Year 1: $132,998 Year 2 and 3: $139,365

If funding not available partnerships with other organizations will be created.

If yes, specify name of organizations providing contributions and status of contribution(s) (confirmed – include letter of support; or pending – indicate contingency plan should funding not be available).

Treasury Board Guidelines
ACCOMMODATION - http://rehelv-acrd.tpsgc-pwgsc.gc.ca/index-eng.aspx
TRAVEL DIRECTIVE - http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/tbm_113/td-dv-eng.asp
MEALS & INCIDENTALS - http://www.njc-cnm.gc.ca/directive/index.php?sid=98&hl=1&lang=eng
INTERNATIONAL MEALS & INCIDENTALS - http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/tbm_113/d-eng.asp
HOSPITALITY - http://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=27228&section=text

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