



Health Canada Santé
Canada Canada

Opioid Response Team
Office of Controlled Substances
November 2018

Application Form

Section 56.1 Exemption for Medical Purposes under the Controlled Drugs and Substances Act for Activities at a Supervised Consumption Site

Office of Controlled Substances
Controlled Substances Directorate
Opioid Response Team
Health Canada

Également disponible en français sous le titre:

Formulaire de demande d'exemption de l'application de la Loi réglementant certaines drogues et autres substances pour des raisons médicale en vertu de l'article 56.1 relativement à des activités dans un site de consommation supervisée

Canada 

Privacy notice

The personal information you provide to Health Canada is governed in accordance with the Privacy Act. The collection of your personal information is authorized under the Controlled Drugs and Substances Act. This information will be used to process your application for a Section 56 exemption for medical purposes under the Controlled Drugs and Substances Act at a supervised consumption site. This information may be used to provide reports to management. The information may also be used for research, planning, audit and evaluation purposes. In limited and specific situations, your personal information may be disclosed without your consent to law enforcement or in accordance with subsection 8(2) of the Privacy Act. Failure to provide the requested information may result in a refusal to process the application. This personal information collection is described in Info Source, available online at oic-ci.gc.ca. In addition to protecting your personal information, the Privacy Act gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact Health Canada's Access to Information and Privacy Coordinator at 613-960-7108 or atip-aiprp@hc-sc.gc.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

Legal obligations and purpose:

This application form is intended for those seeking to be exempted from the Controlled Drugs and Substances Act (CDSA) for the purpose of operating a supervised consumption site for a medical purpose.

As per the CDSA, section 56.1 states that an application for an exemption shall include information regarding the intended public health benefits of the site and information, if any, related to;

- (a) the impact of the site on crime rates;
- (b) the local conditions indicating a need for the site;
- (c) the administrative structure in place to support the site;
- (d) the resources available to support the maintenance of the site; and
- (e) expressions of community support or opposition.

A completed application form will provide elements for each of the above provisions of the CDSA.

Exemptions are issued in the form of a letter and include terms and conditions, as well as expressly setting out activities that can be conducted at a SCS.

Helpful Tips:

- Throughout the present application, references to information provided in additional attached document(s) may be made in lieu of providing the information directly within this application form.
- [An up-to-date log of supervised consumption site applications and their exemption statuses can be found here.](#)
- A checklist can be found at the end of this application to help you ensure completeness of your application prior to sending to hc.exemption.sc@canada.ca.

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① **Applicant information**

Why are we asking for this information? We need this information to understand more about the person or organization that is applying for the proposed supervised consumption site, and who to contact if we need more information.

***If this is a renewal application, please check the box below and complete only Sections 1, 8 and 9.

This is a renewal application.

If this is a joint application, please describe each co-applicant in separate tables below.

Applicant #1

Name of Applicant (Surname/Given Names)					
Title of Applicant					
Name of Applicant's Organization					
Address of Organization					
City		Province/Territory		Postal Code	
Telephone No.					
E-mail Address					
Website Address	Please provide if you would like Health Canada to provide a link to your organization on our website.				
Alternate contacts Please provide the name and contact information (e.g. mobile number and/or e-mail) of any alternate contacts.					
Description of organization and services currently provided (if applicable):					

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Applicant #2, if applicable

Name of Applicant (Surname/Given Names)				
Title of Applicant				
Name of Applicant's Organization				
Address of Organization				
City		Province/Territory	Postal Code	
Telephone No.				
E-mail Address				
Website Address	Please provide if you would like Health Canada to provide a link to your organization on our website.			
Alternate contacts Please provide the name and contact information (e.g. mobile number and/or e-mail) of any alternate contacts.				
Description of organization and services currently provided (if applicable):				

② Proposed site description

Why are we asking for this information? The information required below helps Health Canada structure the exemption. In order for Health Canada to draft an appropriate exemption from the CDSA for medical purposes, it is important to understand the types of services that will be offered at the site, what kinds of treatment services or referral programs are available to clients, and what the general set up of the site will look like.

Name of Site				
Address of Site				
City		Province/Territory		Postal Code
Telephone No.				
Description of current services (if any) offered at the proposed SCS:				
Description of proposed services to be offered at the site (check all that apply):				
<input type="checkbox"/> Supervised injection <input type="checkbox"/> Supervised oral consumption <input type="checkbox"/> Supervised intranasal consumption <input type="checkbox"/> Supervised inhalation				
Please note that applicants are responsible for verifying that this service is in compliance with other applicable federal, provincial and municipal legislation to maintain public health and public safety.				
<input type="checkbox"/> Mobile Unit Please provide information below about where the mobile unit will travel (i.e., where stops will be made along the route and where the mobile unit will be parked outside of operating hours). This information is useful to Health Canada because it helps structure the exemption accordingly.				

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Drug checking

Please note that site policies and procedures should reflect the drug checking process being implemented at the site, including the proper storage and disposal of substances left behind.

Where will drug checking services take place? Onsite Offsite Both

Who will conduct drug checking? SCS clients SCS staff Third party

If third party and offsite, please provide the name/organization, address and method of transport:

Method(s) for drug checking:

- Direct sample test strip
- Urine test strip for analysis of illegal substance sample
- Urine test strip for analysis of urine sample
- Mass spectrometry
- Other

Includes the use of reference standards

If clients choose not to consume drugs that have been tested, will unused illegal substances be handled in accordance with the site's policies and procedures for unidentified substances left behind?

Yes No

If yes, please describe the procedure in section 4 within the description of the policies and procedures for handling substances left behind.

If no, please describe the policy and procedure that will be used to handle discarded drug checking samples.

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Please describe in more detail the process that will be used for drug checking at the supervised consumption site, and include details such as instruments used, persons handling drugs, method of transfer/transport of substances, procedures for how to deal with substances left behind, reference standards and/or quality control measures, data collected, etc.:

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Other proposed services not mentioned above to be offered at the SCS site and/or a description of referral partnerships for relevant services offered off-site - please specify:
e.g., primary healthcare, social services, naloxone kit distribution, etc.

If drug treatment services (e.g., detoxification, drug substitution therapy, etc.) are available on-site or if information on services off-site is available, including direct access and referral-based programs, please describe:

Proposed hours of operation of the supervised consumption services:

e.g., 8 am – 8 pm, Mon – Sat

Please attach a site floor plan and a brief description of the flow of the site (i.e., how will clients move through the site). The site floor plan should clearly demonstrate the layout of the site and identify the storage area for unidentified substances left behind and any security features such as cameras, motion detectors, locks, etc.

Floor plans do not have to be architectural blue prints – a simple diagram will be sufficient. This information is useful to Health Canada as it helps application reviewers visualize the proposed space.

③ Local conditions

Why are we asking for this information? Consideration of the local conditions that support the need for your proposed site, as well as the intended public health benefits to the community where the site will be located is important because it will help you to develop appropriate services for your client population, which will increase the likelihood of success and uptake of the site. This information is also important to Health Canada in assessing the application against the legislative requirements. It also provides important context to decision makers regarding the need for supervised consumption services in your area.

Please check all that apply from the list below and attach any materials to support consideration of local conditions, which may include the following:

Your site-specific definition of “local” in the context of the present application;

Descriptions of the targeted client population to be served at the site, which may include estimates of the number of persons who consume illegal substances, infectious disease rates in relation to problematic substance use, and drug-related overdose deaths;

Number of drug-related overdoses and deaths in the local area relevant to the types of services to be provided at the site;

The intended health and safety impact of the site on the target population and local area; and

Other factors that may impact public health and safety (e.g., local crime rates).

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Please provide a brief summary that describes information listed above, and any other information you feel would be useful and important for Health Canada to consider regarding the local conditions in your area as they relate to the need for a supervised consumption site:

④ Policies, procedures and security

Why are we asking for this information? This information is important for your site to have in place to ensure that the health and safety of everyone at the site will be supported. This information is core to the smooth functioning of a supervised consumption site and can be thought of as the instruction manual on how to operate your site. Health Canada uses information from this section to better understand the request for a proposed site and to ensure legislative requirements are being met regarding the safe delivery of your services and procedures respecting public safety.

Operating procedures of your site describing how the site will function, including measures that will be taken to minimize both the risk of trafficking of illegal substances and any health, safety or security risks to persons at the site should be in place.

Please check off the boxes indicating that the following are in place. Note that key pieces of information are required to be attached to your application.

Policies and/or procedures that outline the roles and responsibilities of staff members and their training requirements (please attach)

Site policies and procedures should clearly indicate who will be responsible for supervising consumption at the site. The site is required to have a Responsible Person in Charge (RPIC). The RPIC is responsible for the site and activities at the site during operational hours. The RPIC is not required to be in the consumption area, but must be located within the same building and on the same floor as the SCS during operating hours. When the RPIC is not on site during operating hours, an Alternate Responsible Person in Charge (A/RPIC) assumes the responsibilities of the RPIC. Please note that you may have more than one A/RPIC, so these personnel may be assigned as appropriate for your particular site needs and operational model.

The organization must inform and train the RPIC, A/RPIC(s), key staff members and all staff members on their roles and responsibilities. You will need to maintain a training log that indicates who has been trained and when the training has been completed. If the persons supervising consumption are not regulated health professionals (e.g., nurse, doctor, paramedic, etc.), please provide details regarding any extra training that will be required of these personnel. This should include a description of the overdose training that must be taken by non-medical staff involved in consumption supervision.

Policies and/or procedures for disposal of sharps and biohazardous materials

The site policies and procedures for the disposal of biohazardous waste may be adapted from or aligned with the approved policies and procedures used by the health authority or organization operating the site. A copy of this procedure does not need to be provided with your application; however, there should be one in place for the site.

Policies and/or procedures for addressing unidentified substances left behind (please attach)

A site-specific policy with procedures on how to deal with unidentified substances left behind at the site should be provided. These procedures should include a description of who is responsible for the substances, how they will be handled, where they will be stored (in a locked location such as a safe, lockbox, double-locked drawer, etc.), and guidance for staff on how to appropriately transfer substances to law enforcement. Records for any unidentified substance found at the site are required to be maintained at the site and include the following information:

- a) the date the substance was found;
- b) the location where the substance was found;
- c) the name of the staff member who packaged and stored the substance;

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- d) the date the local police were contacted to request removal of the substance;
- e) the name and signature of the officer who removed the substance; and
- f) the date the substance was removed from the site.

The policies and procedures to address unidentified substances left behind submitted to the Office of Controlled Substances (OCS) must include either a copy of the record-keeping form or reference to the logbook (and the tracked information) that will be used by staff in such instances.

Policies and procedures for loss or theft of unidentified substances left behind (please attach)

The site should have policies and procedures in place to prevent the loss or theft of unidentified substances left behind at the site, which includes record-keeping requirements. Please note that loss or theft of any unidentified substance left behind should be reported to police immediately and to the OCS within 24 hours. You may use the Health Canada loss or theft report form or, if you prefer, you may create your own form (<https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/controlled-substances/compliance-monitoring/loss-theft-forgery.html>).

Loss or theft report forms may be submitted by email to: hc.exemption.sc@canada.ca.

The policies and procedures to address the loss or theft of unidentified substances left behind submitted to OCS in your application must include a copy of the reporting form that will be used by staff in such instances, whether it is a copy of your own site's form or a copy of (or hyperlink to) the standard loss/theft form from Health Canada.

Policies and/or procedures that outline security measures that will be taken to minimize risks to the health, safety and security of all persons at the site (please attach)

The SCS should have a main door that locks. With respect to the SCS space, there are no prescribed physical or security specifications that need to be met. Applicants are responsible for ensuring that adequate measures are in place at the site for the security of staff and clients at all times. Security features and physical layout may be designed in a manner that is appropriate for your particular site needs and operational model. Examples of security measures that have been used in SCSs include:

- video surveillance;
- restricted or controlled access areas;
- locked or unidirectional doors separating rooms within the facility;
- keycard/keypad/fob/key access within the site;
- panic alarms;
- security alarms; and
- security personnel on site.

In addition, there should be a system in place for keeping records of the entry and exit of clients and visitors from the consumption area of the site.

Site policies and procedures should clearly indicate the person (or job title) who will be responsible for the distribution of site security elements (e.g., keys, fobs) used for access control. This would include confirmation that records will be kept regarding security element distribution, as well as the circumstances whereby security elements would be changed (e.g. locks changed or fobs deactivated if they are lost or stolen).

A description of records maintained at the site

Site records must include instances of unidentified substances left behind, loss or theft of unidentified substances left behind, and entry and exit of clients from the consumption room or area. Records should be

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retained for a minimum of 2 years; however, it is the responsibility of the applicant to ensure that all requirements set out by other applicable federal, provincial and municipal legislation relevant to SCS services are met. A copy of these records does not need to be provided with your application; however, by checking the box, you acknowledge that these records must be maintained at the site and available to OCS if requested.

Provincial or territorial government guidance for the establishment of a supervised consumption site (if any) have been considered and reviewed

A copy of this guidance does not need to be provided with your application, however, please acknowledge that this type of guidance has been considered and reviewed (if any) by checking the box.

Provincial or territorial government guidance does exist

For the purpose of openness and transparency, please indicate by checking the following boxes if you are willing to allow Health Canada to publish segments of your policies and procedures on our website:

Policies and/or procedures that outline the roles and responsibilities of staff members

Policies and/or procedures outlining staff training requirements

Policies and/or procedures for disposal of sharps and biohazardous materials

Policies and/or procedures for addressing unidentified substances left behind

Policies and/or procedures for loss or theft of unidentified substances left behind

A description of records maintained at the site

Provincial or territorial government guidance for the establishment of a supervised consumption site (if any) have been considered and reviewed

⑤ **Personnel**

Why are we asking for this information? It is useful for Health Canada to know who is responsible for the operation of the site and who to contact if there are issues or questions.

A criminal record check and resume are required for the responsible person in charge (RPIC). It is common practice to request a criminal record check in cases where someone is working with vulnerable populations. For the purposes of this application, criminal record checks are only required for the RPIC and not for other staff at the site. Although this is no longer an OCS requirement for A/RPICs, applicants may continue the practice of requesting criminal record checks as per internal policies and procedures if they so desire in order to provide a safe environment to all clients they serve.

Responsible Person in Charge (RPIC) Information

Please provide a valid criminal record check and resume for the designated RPIC. Due to the time constraints that can be encountered when obtaining a criminal record check, please note that your application can be submitted while you wait for the criminal record check to be completed.

The criminal record check must be a document issued by a Canadian police force in relation to the RPIC, stating whether, in the 10 years before the day on which the application was made, the person was convicted as an adult in respect of a designated substance offence or designated criminal offence. If the RPIC has ordinarily resided in a country other than Canada in the 10 years before the day on which the application was made, a document issued by a police force of that country stating whether in that period the person was convicted as an adult for an offence committed in that country that, if committed in Canada, would have constituted a designated substance offence or a designated criminal offence must be submitted.

Name (Surname/Given Names)			
Professional designation and regulatory body licence number, if applicable: e.g., Medical doctor, CPSO #			
Proposed Schedule – Work Hours and Days e.g., 8 am – 8 pm, Mon – Sat			
Telephone No.		E-mail Address	

Criminal Record Check attached to the application; or
Criminal Record Check to be sent at a later date.

⑥ Consultation report and letter of opinion

Why are we asking for this information? We need this information to understand the efforts that have been made to engage with the community to inform them of the proposal and ensure that the voices of community members have been heard.

A letter of opinion from the provincial or territorial Minister of Health is an item for consideration when rendering a decision on an SCS application. A letter of opinion would be additional supporting information for your application but is not mandatory.

Attached to this section of the application is:

The community consultation report and all related documents.

The consultation report must include a description of consultation activities that were undertaken for the proposed site. Results from the consultations, including all feedback and comments that were received, should be provided. Any advertising materials, forms or documents used for collecting opinions may be included as supporting documentation. Examples of consultation tools include:

- open house
- online survey
- general email account
- SCS website
- information meetings
- presenting at community association meetings
- flyers
- door-to-door canvassing

In the case where concerns were raised during the community consultation, a description of measures to address these concerns.

A letter of opinion from the provincial or territorial Minister responsible for health or the Minister responsible for the delivery of supervised consumption services.

Yes No

⑦ **Financial plan**

Why are we asking for this information? This information helps Health Canada understand whether the site has the resources needed to operate safely and effectively.

Please provide a brief summary that describes the financial plan and funding mechanism or model that will be in place:

Information to be attached to this section of the application may include:

- financial statements or audits for the organization applying;
- documentation confirming sources of funds (public or private);
- confirmation of funding commitments; and/or
- budget proposals.

⑧ Renewal (if applicable)

Attached to this section of the application is (check all that apply):

- information relating to changes in the policies and procedures;
- information relating to a change in the designated RPIC;
- information relating to changes in the floor plan and/or security measures;
- other supplemental information relating to changes that could impact public health and safety; and/or
- additional community consultations or views, if any.

If there are no changes related to the continuance of activities at the site, please check here.

⑨ Applicant statement

The information provided in this form is required by Health Canada under the authority of the Controlled Drugs and Substances Act for the issuance of a Section 56.1 Exemption for activities at a supervised consumption site for a medical purpose. The collection and use of personal information is in accordance with the federal Privacy Act. A refusal to provide the information requested on this form may result in the application being declined.

I hereby certify that all information and supporting documents provided with this application are to the best of my knowledge correct and complete.

Name of applicant (please print): _____

Title of applicant (please print): _____

Signature of applicant: _____ Date: _____

⑩ Submitting application

Application can be sent to:

By e-mail: hc.exemption.sc@canada.ca

By mail: Authorizations Division
Office of Controlled Substances
Controlled Substances Directorate
Opioid Response Team
Health Canada
161 Goldenrod Driveway, AL0300B
Ottawa ON K1A 0K9

Should you have any questions at any point in the application process, please contact us at hc.exemption.sc@canada.ca.

Checklist for a supervised consumption site application

This checklist is provided to assist you in ensuring that all the required information has been attached to your application for a supervised consumption site, in addition to the information provided within the application form itself. Incomplete applications will be put on hold until the required information is received.

✓	Section	Attachments
	Section 1: Applicant information	<ul style="list-style-type: none"> ○ Description of services currently offered by organization
	Section 2: Proposed site description	<ul style="list-style-type: none"> ○ Description of services currently offered at the proposed site ○ Description of all SCS services that will be offered at the proposed site ○ Site floor plan and description of the flow of the site
	Section 3 Local conditions	<ul style="list-style-type: none"> ○ Descriptions of target client population ○ # of drug-related overdoses and deaths in local area ○ Baseline crime data for the local area ○ Intended health and safety impact of site on target population, general public, and local area
	Section 4 Policies, procedures, and security	<ul style="list-style-type: none"> ○ Roles and responsibilities of staff members and training requirements ○ P&Ps for addressing unidentified substances left behind + record-keeping form ○ P&Ps for loss or theft of unidentified substances left behind + reporting form ○ P&Ps outlining security measures taken to minimize risks + client or visitor entry and exit log
	Section 5 Personnel	<ul style="list-style-type: none"> ○ RPIC contact information, resume, and criminal record check (+ foreign CRC if applicable)
	Section 6 Consultation report & letter	<ul style="list-style-type: none"> ○ Community consultation report (description of activities and results, etc.) and all related documents ○ Description of measures to address concerns ○ Letter of opinion from the Provincial/Territorial Minister for Health or the Minister responsible for the delivery of SCS services (optional)
	Section 7 Financial plan	<ul style="list-style-type: none"> ○ Summary of funding mechanism or model ○ Summary of financial plan
	Section 8 Renewal (if applicable)	<p>If applicable:</p> <ul style="list-style-type: none"> ○ information relating to changes in the policies and procedures; ○ information relating to a change in the designated RPIC; ○ information relating to changes in the floor plan and/or security measures; ○ other supplemental information relating to changes that could impact public health and safety; and/or ○ additional community consultations or views, if any.
	Section 9 Applicant statement	<ul style="list-style-type: none"> ○ Signed applicant statement
	Section 10 Submitting application	N/A