

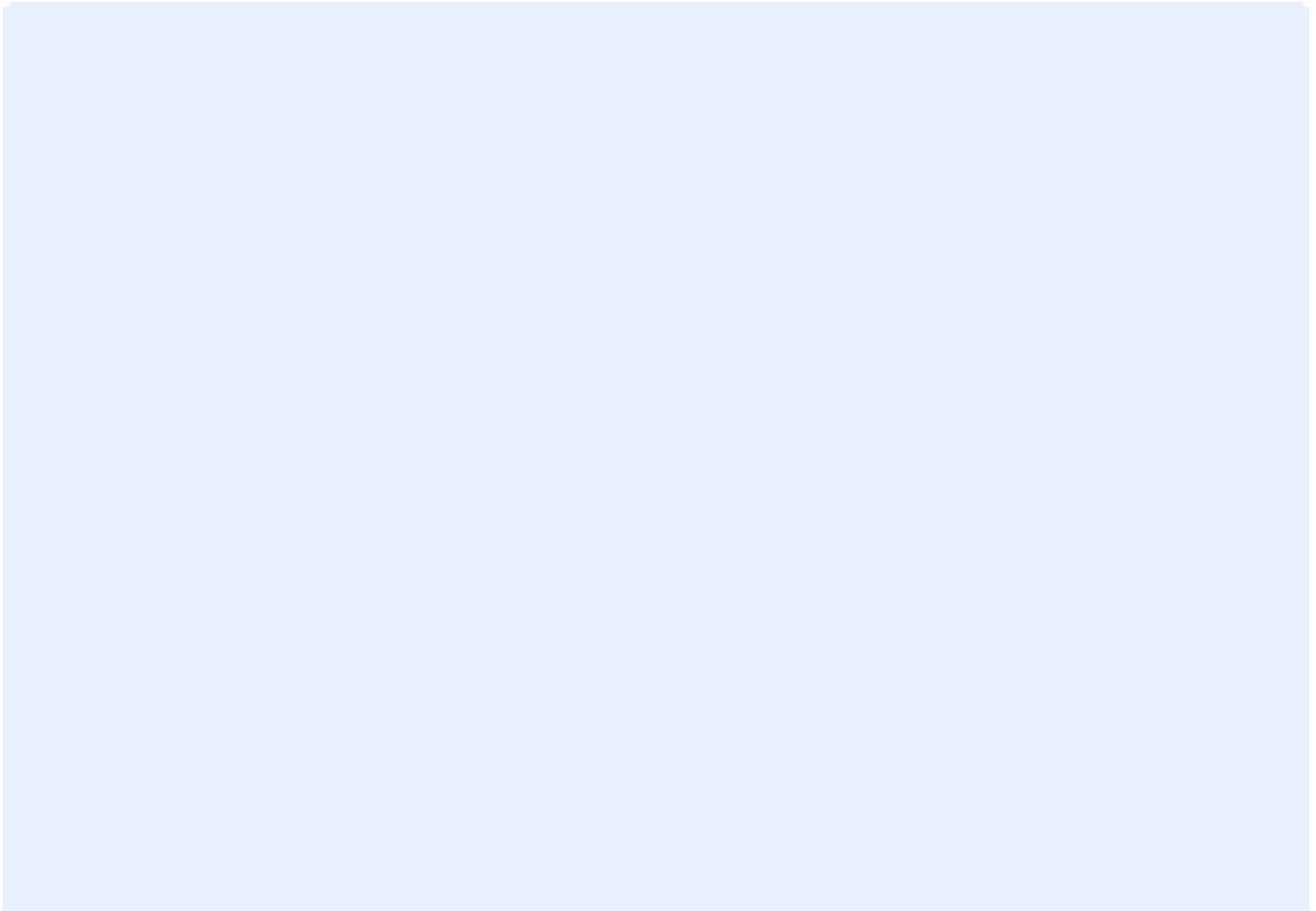


Australian Government
Department of Health
Office of Drug Control

Guidance: Completing a Licence Application Form

Filling in the form

Version 2.1, July 2020



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Version control

Updates to this document will occur automatically on the Office of Drug Control website and the revision table below will list the amendments as they are approved.

Date	Version	Amendments	Approved by
30 October 2016	1.0	Initial publication	ODC
06 February 2016	1.1	Removal of paragraph relating to the supply chain and minor content amendments under Annex D	ODC
01 January 2020	2.0	Amendments to reflect Phase One of the legislative change arising from the Review of the <i>Narcotic Drugs Act 1967</i>	ODC
01 July 2020	2.1	Amendments to reflect fees and charges implemented on 1 July 2020	ODC

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Introduction

This guidance is for stakeholders who are applying for a new licence under the *Narcotic Drugs Act 1967* to cultivate, produce and/or manufacture cannabis or cannabis material for the purposes of patient supply or research using the **online form** available on the Office of Drug Control's (ODC) website or the **downloadable flat forms**.

The facility where authorised activities involving cannabis are proposed to take place must be located in Australia. You must be an Australian business entity or individual residing in Australia to apply for a licence.

It is your responsibility to meet all requirements in order for the Office of Drug Control (ODC) to grant a cannabis licence. ODC does not facilitate business arrangements, nor provide any business advice or support.

All information provided in the application must be truthful and accurate. Legal sanctions apply to any applicant knowingly providing incorrect information or withholding information that may be relevant to the decision. ODC verifies information in an application with state and territory authorities, including law enforcement agencies.

It is important that you read the published guidance and guidelines prior to attempting to complete the application. You should not submit the application form until all information is provided.

It is recommended that you retain a copy of the application for your records.

ODC will review each received application to ensure it is complete and incomplete submissions will be rejected.

You must pay the relevant application fee before assessment begins and you will receive an invoice setting out the amount payable after ODC has determined the application to be complete.

Any fee attracted by the application is non-refundable.

Even if 'complete', ODC may need additional information and clarification during the assessment. You will be contacted if this is the case. You must provide all additional information that is requested.

If additional information is requested, a licence cannot be granted until that information has been provided and ODC is satisfied all concerns have been addressed.

This application cannot be used to vary an existing licence.

Completing the online application modules (smart form)

Applicants are able to apply for a cultivation, production or research licence relating to cannabis for medicinal purposes through the online application available on the ODC website <https://www.odc.gov.au/licence-and-permit-application-forms-0>. This form can also be used if you are seeking a manufacture licence but ONLY if you are also applying for a cultivation and/or production licence or a research licence. If you are applying solely for a manufacturing licence, visit the manufacturers section of the website.

Downloadable application modules (flat forms)

It is recognised that in exceptional circumstances, stakeholders may prefer downloadable versions of application forms to better consider the questions or incorporate aspects of the forms into their proprietary documentation or operating procedures. For the benefit of the sector, the Office of Drug Control (ODC) provides downloadable versions of the forms and modules on the ODC website.

The term 'downloadable application', as used in this document, refers to the action of creating a cannabis licence application package by:

1. emailing ODC to discuss your requirement to submit a downloadable application
2. downloading the relevant flat forms and modules from the ODC website
3. completing the modules on a local PC
4. storing/compiling the completed application modules and all applicable evidence on storage media
5. submitting the digital storage media (soft copy) to ODC as an 'application' for processing.

ODC may accept flat form licence applications in digital media (soft copy) or a hardcopy but strongly advises against this approach in favour of the online licence application form.

If you intend to submit a soft or hard copy application, you need to ensure that all required application modules are completed and combined with the appropriate evidence. Omitting any module or evidence may render the submission incomplete and the application will be rejected.

Before doing this it is important that you discuss your intentions and reasons for doing so with ODC by emailing mcs.application@health.gov.au or calling (02) 6289 4628 during business hours.

Making an application

The modules that make up a licence application are located on the ODC website and can be downloaded from the application launch page.

A downloaded cannabis licence application **must** be composed of four parts (outlined below). These must be completed, compiled and submitted together with all evidence required.

**1. Cannabis licence application form
(main body)**

+

2. Cannabis licence details module(s)

+

3. Security details module

+

**4. Risk management and standard
operating procedures and policies
module**

= Valid application

You must select the relevant licence variants in steps 1 and 2. These will dictate the nature of the licence being applied for.

Step	Selections available	Component		
1.	You must decide whether you are applying as an individual, a body corporate or a crown agency	Cannabis licence application form (main body)		
		Applicant is an individual	Applicant is a body corporate	Applicant is a crown agency

+

2.	You must decide the type of licence required. Multiple licences may be applied for together however a medicinal cannabis licence and cannabis research licence cannot be selected in the one application	Cannabis licence details module		
		Medicinal cannabis licence	Cannabis research licence	Manufacturing licence for narcotic drugs

+

3.	All applicants to complete	Security details module		
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+

4.	All applicants to complete	Risk management and standard operating procedures and policies module		
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Example 1. If you are applying as a Body Corporate seeking a cannabis licence for research purposes the following application components in **light blue with an asterisk*** will need to be accessed from the ODC website. All parts need to be completed and submitted together with the appropriate evidence in order to make a valid application.

Step	Selections available	Component		
1.	You must decide whether you are applying as an individual, a body corporate or a crown agency	Cannabis licence application form (main body)		
		Applicant is an individual	Applicant is a body corporate*	Applicant is a crown agency

+

2.	You must decide the type of licence required. Multiple licences may be applied for together however a medicinal cannabis licence and cannabis research licence cannot be selected in the one application	Cannabis licence details module		
		Medicinal cannabis licence	Cannabis research licence*	Manufacturing licence for narcotic drugs

+

3.	No choices	Security details module*		
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+

4.	No choices	Risk management and standard operating procedures and policies module*		
----	------------	---	--	--

Example 2. If you are an individual seeking a cannabis licence for medicinal cannabis and a manufacturing licence for narcotic drugs, the following application components in light blue with an asterisk* will need to be requested from ODC. All parts need to be completed and submitted together with the appropriate evidence in order to make a valid application (covering that selection).

Step	Selections available	Component		
1.	You must decide whether you are applying as an individual, a body corporate or a crown agency	Cannabis licence application form (main body)		
		Applicant is an individual*	Applicant is a body corporate	Applicant is a crown agency

+

2.	You must decide the type of licence required. Multiple licences may be applied for together however a medicinal cannabis licence and cannabis research licence cannot be selected in the one application	Cannabis licence details module		
		Medicinal cannabis licence*	Cannabis research licence	Manufacturing licence for narcotic drugs*

+

3.	No choices	Security details module*		
----	------------	---------------------------------	--	--

+

4.	No choices	Risk management and standard operating procedures and policies module*		
----	------------	---	--	--

Online application. It is strongly recommended that applicants utilise the online licence application. **Special arrangements must be reached with ODC** if you intend to submit a manual application using flat forms. The relevant ODC team may be contacted by emailing mcs.application@health.gov.au.

Those considering applying for a licence using flat forms should be aware of the following limitations of this approach:

- application modules stored on a local PC or network may go out of date and no longer be valid
- soft copy applications using flat forms are more difficult to complete than the online equivalent causing a higher likelihood of errors and incomplete application submissions
- a soft copy application cannot be validated for correctness before submission (which occurs automatically in the online application)
- soft copy licence applications must be posted to ODC and may be subject to loss, damage or delay in transit. The online form submits electronically immediately after completion

Additional limitations with a soft or hardcopy application include:

- licence applications sent via mail to ODC will take longer to reach and be processed by ODC
- licence applications containing hand written entries may be difficult to read and cause delays in processing

It is important that any applications not submitted through the online application form (smart form) include an index that links the evidence with the question in the modules.

Preparing to apply

Application Do's and Don'ts

Do	Don't
Consult the <i>Narcotics Drugs Act 1967</i> and <i>Narcotic Drug Regulation 2016</i> before starting	Apply without consulting the background legislation
Read and understand the guidelines and guidance documents before applying	Apply without understanding the requirements of the scheme
Understand the applicable fees and charges	Apply without knowing the regulatory fees and charges
Ensure that the information provided in the application is accurate, truthful and complete	Alter facts to fit your application
Try to complete the application at one time. Have the necessary copies of evidence ready at the time you apply	Start the application without having the data ready. Incomplete applications will not be accepted and will not be held inactive in draft for more than 14 calendar days
Prepare to answer additional questions or provide information to support the application	Undertake any actions on the assumption the application will be successful. You will be advised in writing if a licence is granted
Withdraw your application if you change your mind or find you cannot pay the fee	Let your application continue processing if you have changed your mind or do not intend to pay the fee
Consider the reasons for your application being rejected before applying again	Apply again without addressing our concerns if your application was rejected

Consider having the following documents ready before you commence the application:

1. [Site aerial plan](#)
2. [Site floor plan](#)
3. Your (the applicant's) completed Informed Consent form
4. Completed Informed Consent forms for directors and business associates and any other persons with decision making authority (refer to [Annex C](#) for further information on who should complete the form)
5. [Business resume and current business statement](#)
6. [Security plan](#)
7. [Risk management plan and standard operating procedures and policies](#)

Applicant and agent

For the purposes of this guidance, the term 'agent' refers to the person or persons who completes informational or part of the form and/or submits the application on your behalf.

The term 'applicant' refers to the person seeking the licence. You may be both the applicant and the agent.

Regardless of the circumstances, the applicant is accountable for the accuracy of all information contained in the application.

Assistance

You can seek assistance from ODC on the completion and submission of the application by contacting (02) 6289 4628 during business hours or by emailing MCS.application@health.gov.au. ODC contact cannot:

- provide advice on whether you require a licence under the law
- provide business advice
- submit an application on your behalf
- give approval
- accept payment

Retaining a copy of your application form

It is recommended that a copy of the application in its final form is retained for your reference.

Starting a new downloadable application (flat form)

1. Email MCS.application@health.gov.au to discuss your requirement to use the downloadable flat form.
2. Visit the ODC website at <https://www.odc.gov.au>
3. Select Medicinal Cannabis > Application forms and guidance > Flat forms
4. Download the fillable version of the relevant licence application forms and modules you require to develop a complete application.

As previously mentioned, you must decide the type of application and the activities to be authorised in order to select the relevant licence application forms and modules. It is important to note that this decision affects the application questions from the point of the selection (in order to cover the necessary legislative requirements).

Starting a new online application (smart form)

1. Visit the ODC website at <https://www.odc.gov.au>
2. Select Medicinal Cannabis > Application forms and guidance > Apply online
3. Work through the online application

Guidance on key questions

Complete the questions in all selected modules. Guidance can be found on key questions in the annexes of this publication as follows:

Application Module	Annex
Application body corporate/individual/crown agency – <i>applicant</i>	Annex A
Application body corporate/individual/crown agency – <i>site</i>	Annex B
Application body corporate/individual/crown agency – <i>Fit and Proper Person</i>	Annex C
Licence module (manufacturing, medicinal cannabis, cannabis research)	Annex D
Security plan module	Annex E
Risk management and standard operating procedures and policies	Annex F

Submitting your downloadable application

Hard and soft copy applications must be received at the following address:

Drug Control Section
Office of Drug Control
PO Box 100
Woden ACT 2606

The applicant is responsible for the delivery of the application to the aforementioned address. The sender should be identified on the parcel.

Correcting an application after submission

Once the licence application form has been submitted, it cannot be altered and you will need to discuss any changes with ODC. If you become aware that a minor change to the form is required then you should notify ODC immediately by emailing MCS.application@health.gov.au.

For the purposes of this document, a minor change to a submitted application is the correction of basic information contained in the application, e.g. correction of a phone number or misspelling of a suburb.

In contrast, a substantial change is one that may alter the possible outcome of the application, e.g. the change is a selection from 'yes' to 'no', the removal of an attachment or changes to the site information. ODC will not accept substantial changes to a submitted application and will request that you submit a new licence application form. The applicant may need to pay the relevant application fee again.

Submitting a concurrent application

Circumstances may arise where an applicant requires both a cannabis research licence and a medicinal cannabis licence. This licence combination requires two applications, however if both applications are submitted together, it is acceptable for the applications to reference the same set of supporting evidence. It is best you contact ODC at MCS.application@health.gov.au for assistance before attempting to submit a concurrent application.

Annex A – Section 1: Applicant details

Questions relating to	Brief description
All questions in this section	<p>The applicant is the party to whom the licence will be granted if the application is successful. All information in this section refers to the applicant.</p> <p>Note: Please ensure this is not mistakenly entered as the person(s) completing the form on behalf of the applicant (if such an arrangement occurs).</p> <p>Irrespective of the person(s) completing the form, the applicant is accountable for the accuracy of the information entered and submitted.</p>
ABN/ARBN/ACN:	All body corporate and crown agency applicants must submit their unique business number so ODC can confirm their business identity. An individual may also submit their unique business number if applicable.
Please attach three certified proof of identity documents consisting of a combination of the following, with at least one from Category A (as defined under regulation 4 of the <i>Narcotic Drugs Regulation 2016</i>):	These certified documents are required to legally verify the identity of an applicant who is a natural person (individual). These documents must be certified by a person who is prescribed under regulation 4 of the <i>Statutory Declaration Regulations 1993</i> .

Annex B – Section 2: Site details

Questions relating to	Brief description
Site address and land parcel identification (e.g. Lot/Block/Section)	This information should detail the exact address and location of the proposed site so ODC can precisely identify location of the site. The way a parcel of land is identified alters between states and territories.
Site area	ODC will assess that statements indicate the overall area of the premises for licencing to ensure the area is adequately identified. This would normally be measured in hectares. However, for smaller sites (such as research institutions), dimensions in metres squared may be represented as a fraction of a hectare. The actual size in metres may be inferred in the plans or may be determined in subsequent questions from ODC.
Latitude S Longitude E	The Global Positioning System coordinates (as precisely as possible) of the cannabis site/s are required, so ODC can precisely identify the location of the site. In general, the coordinates should give the centre point of hands-on cannabis related activity being conducted under licence/permit.
Is the land owned by the applicant?	ODC has no preference regarding ownership or leasehold on land. However, the information provides ODC with an understanding of the control the applicant has over the land and is important to know in the event that issues emerge.
If the land is leased, please provide the name and address of the lessor	A statement detailing the name and address of the lessor (the party from whom the site is leased) is required. ODC may contact the lessor for access to the site or other issues if necessary. The lessor must be aware of the proposed activities at the site.
Please provide details on how the land, premises and facilities can be accessed for inspection purposes	It is a condition of the licence that ODC is provided unfettered access to the site during business hours. These access arrangements are required in the application to ensure that the applicant is prepared for, and can facilitate, unannounced inspections. For the purposes of inspections and monitoring, ODC will always require access, during business hours. Failure to allow authorised inspectors entry to the land, premises and facilities will be a breach of conditions and may be grounds for revocation of the licence.

Questions relating to	Brief description
<p>Provide the addresses of all premises at which activities relating to the proposed licensed activities will be carried out (if there is more than one external site, please attach)</p>	<p>ODC accepts that a business may have more than one site where authorised activities may occur. Details of these locations are required so that ODC can identify the physical location of the site and the activities to be performed there and assess the risks associated with the locations. These matters are factored into the nature of the approvals granted and ODC's inspection program. You should be specific to the steps associated with any one site in relation to when cannabis is present at that site, or a site where records are located and employee management occurs.</p>
<p>Please attach</p> <ul style="list-style-type: none"> • A site plan showing how the land will be used for the proposed licensed activities • A floor plan of the premises and facilities where the licensed activities will be undertaken 	<p>A site plan and floor plan should be attached which shows the site and a breakdown of where each activity will be undertaken. (A site plan should be submitted for each location to be licenced). ODC will assess this information to understand the business operations and physical construction of the site. This information is also used to validate consistency of information provided about the location and your proposed licence activities.</p>
<p>Has the applicant applied for, or does the applicant intend to apply for, another licence under the <i>Narcotic Drugs Act 1967</i></p>	<p>It is important that ODC understands how this application relates to other authorised activities involving narcotics that may have been approved and conducted or are not yet authorised but are planned. By selecting 'Yes' you are presented with a prompt to identify any intended applications i.e. those that are currently planned for but not yet executed and are relating to narcotics (cannabis/opiates). The answer 'None' may be provided if no further applications are intended at this time.</p> <p>This will be followed by questions regarding existing applications lodged with ODC for authorised activities involving narcotics (cannabis/opiates). Details including the licence number and type will be required. This refers to the approval details provided by ODC in relation to these applications.</p>

Annex C – Section 3: Fit and Proper Person details

[Guidelines covering Fit and Proper Persons and Suitable Staff](#) are provided on the ODC website and should be read and understood before completing the application form.

Truthfulness

The fit and proper person checks are extensive and require the disclosure of a significant depth of information. While ODC accepts that mistakes can be made, it is important to endeavour to be comprehensive in responding to the information requested.

The applicant must ensure that persons identified in this application are provide a completed Informed Consent form and are cognisant of the possibility that ODC may approach law enforcement and other agencies to obtain relevant information.

If a matter later comes to light that, if known at the time, would have affected your ability to meet the fit and proper requirements, your licence may be revoked.

It is considered an offence if a person provides false or misleading information (see section 137.1 of the *Criminal Code Act 1975* (Cth)).

Importantly, all information you provide is judged case by case. Failure to meet some requirements relating to fit and proper persons does not, mean that your application will be automatically unsuccessful. ODC will consider the circumstances and context of the information and may still determine that the applicant is fit to hold a cannabis licence.

The Applicant is a Natural Person (individual)

Questions	Brief description
Have you been convicted, at any time, of an offence against a law of the Commonwealth, a State or a Territory, or another country?	<p>ODC must consider any prior convictions in deciding whether to grant a licence. You must advise of all prior convictions, whether or not they are spent and provide any relevant details including:</p> <ul style="list-style-type: none"> • when the conviction was recorded • the nature of the conviction • the jurisdiction where the conviction was recorded • the consequence of that conviction, for example a custodial sentence <p>ODC will validate your response with law enforcement agencies. Failure to give an accurate account may result in rejection or licence revocation if conflicting information comes to light at a later date.</p>
Have you engaged in conduct (that may or may not have led to a conviction) constituting a serious offence involving cultivation, supply, or use of cannabis?	<p>If you answer 'Yes' to this question, ODC will request details under Section 14J of the <i>Narcotic Drugs Act 1967</i> after your application has been submitted. This allows for protections against self-incrimination which means ODC cannot provide these details to police for investigation.</p>

Questions	Brief description
	<p>Do not include any details of the conduct in the application form as protections against self-incrimination do not apply and ODC may be required to disclose to law enforcement agencies depending on the nature of the offences.</p> <p>If you answer 'Yes', you must provide a full disclosure of the offence(s) in order for the ODC to be able to consider the grant of a licence. If it is discovered that you have not fully disclosed all conduct that would constitute a 'serious offence', these are grounds for refusal of the application or revocation of the licence.</p> <p>Full disclosure of all conduct constituting a serious offence is not a guarantee of gaining a licence. ODC will take the nature and circumstances of the offences into account in determining whether or not to grant the licence.</p>
<p>Have you ever had a civil penalty imposed upon you, at any time, under a law of the Commonwealth, a State or a Territory?</p>	<p>You must state if you have had a civil penalty imposed on you and provide relevant details of the penalty, including:</p> <ul style="list-style-type: none"> • when the penalty was imposed • the nature and reason for the penalty • the jurisdiction that issued the penalty • the financial value of the penalty
<p>Have you ever had a licence or permit (however described) revoked or suspended under a law of the Commonwealth, a State, a Territory or another country, being a law relating to the prohibition or regulation of drugs?</p>	<p>You must state if you have ever had a licence or permit revoked or suspended relating to the prohibition or regulation of drugs from the Commonwealth, State or Territory, or another country, and provide details of this including:</p> <ul style="list-style-type: none"> • the law that the licence or permit was issued under • the activities authorised by the licence or permit • the jurisdiction that revoked or suspended the licence or permit • the reason/s for the revocation or suspension • the period of the suspension <p>ODC will consider a statement including details of the regulatory activity, the penalty imposed (if any) and the value of the penalty linked to previous or current revocations and suspensions of licences in relation to drugs. This may demonstrate that you are not a fit and proper person to hold a cannabis licence.</p>

Questions	Brief description
<p>Do you have any connections or associations with other people that may affect your reputation, character, honesty, or professional or personal integrity:</p>	<p>There are two elements to this question – firstly, the people you have a connection or association with and, secondly, persons that may have the ability to adversely affect your honesty or professional decision making or personal integrity. The types of connections or associations you should include are family members, business partners, close friends and/or your immediate circle of close acquaintances. This may include, but is not limited to, persons that you are involved who can be described as cohorts, ‘mates’, special interest groups or clubs.</p> <p>Some examples of associations that ODC may seek further information about are your links with any person:</p> <ul style="list-style-type: none"> • with known links to criminal or outlawed organisations • with a criminal history or served a custodial sentence • who has had a civil penalty imposed <p>You should include any family member who have known links to a criminal organisation or any business associate(s) convicted of a crime.</p> <p>A statement is required to identify persons (connections and associations) who may have an effect on you and influence your operation of a business with access to and/or control of cannabis or other narcotics.</p> <p>ODC will liaise with law enforcement agencies to validate this information and failure to identify an association that may affect your reputation, character, honesty, or professional or personal integrity may result in application rejection or the revocation of a cannabis licence if such information comes to light at a later date.</p>
<p>List below each person who holds a relevant financial interest, or who is entitled to exercise a relevant power (either in their own right on behalf of another person), in relation to:</p> <ol style="list-style-type: none"> 1. your business undertaking the activities to which this application relates; and/or; 2. any other business you undertake and provide a substantial portion of your income. 	<p>You need to provide a list of all the people that can influence your business due to the financial interest they have or because they hold a power over, or can substantially influence decision making in relation to this business, or any other business in which you are actively involved. The applicant must explain the relationship between other businesses and how that income relates to the potential cannabis licence you are applying for.</p> <p>You need to outline how the person(s) holding financial interest can exert power over your business (in the event a cannabis licence was to be granted). Such persons may negatively influence the</p>

Questions	Brief description
	<p>decision making process if they:</p> <ul style="list-style-type: none"> • have known links to criminal organisations • have a criminal history or served a custodial sentence • have had a civil penalty imposed on them • have a history of bankruptcy
<p>Are there any matters that may affect whether you are of good repute, relating specifically to your character, honesty and professional and personal integrity:</p>	<p>This question is concerned with identifying any matters that may have the ability to adversely affect your honesty or professional decision making or personal integrity ranging from disciplinary action to connections or associations. This may be a risk factor in the overall compliance of the facility in the event a licence was granted.</p> <p>For example, if you have held a professional qualification and have been subject to disciplinary action by the relevant regulatory body, you should provide details of the action including:</p> <ul style="list-style-type: none"> • when the disciplinary action was taken • the reason for the action • the outcome of the action <p>The types of connections or associations to persons with which they are involved include cohorts, 'cronies', 'mates', special interest groups or clubs.</p> <p>Some examples of association that ODC may seek further information about are between that person and any person:</p> <ul style="list-style-type: none"> • with known links to criminal or outlawed organisations • with a criminal history or served a custodial sentence • who has had a civil penalty imposed <p>This should also include any family member who has known links to a criminal/outlawed organisations or a business associate who has been convicted of a crime.</p> <p>ODC will liaise with other agencies to validate this information and failure to identify an association that may affect your reputation, character, honesty, or professional or personal integrity may result in application rejection or the revocation of a cannabis licence if such information comes to light at a later date.</p>

Questions	Brief description
Do you hold, or have you previously held, a licence issued under the <i>Narcotic Drugs Act 1967</i> (Cth)	<p>If you have ever held a licence issued under the <i>Narcotic Drugs Act 1967</i> (Cth) you should provide:</p> <ul style="list-style-type: none"> the licence number the licence type the licence status (whether the licence is current, expired, revoked or suspended)
Are there any issues you wish to bring to the attention of ODC relating to your compliance with the <i>Narcotic Drugs Act 1967</i> . If there are no compliance issues, please write 'Nil'	<p>If you have previously engaged in activities under the <i>Narcotic Drugs Act 1967</i>, you should detail any issues of non-compliance. For example, unexplained loss of a controlled drug, non-compliance with an import permit or any offences you committed under the Act.</p> <p>ODC will consider this statement in determining if the applicant is a fit and proper person to hold a cannabis licence.</p>
 Please attach a completed Informed Consent form for the applicant.	ODC must be provided with a completed Informed Consent form. ODC may approach law enforcement and other agencies to obtain relevant information.
 Please attach a resume detailing your previous business experience.	An extensive resume is not required, however, you should include a summary of your business experience.
 Please attach evidence (e.g. a bank statement or audited financial statement) that you have a sound and stable financial background and that there are no financial circumstances that may limit your ability to comply with a licensee's obligations under the <i>Narcotic Drugs Act 1967</i> :	<p>The request for financial background evidence may be met by providing one of the following examples:</p> <ul style="list-style-type: none"> a statement from a financial institution(s) showing financial reserves a financial audit report by a suitably qualified person (with a positive outcome) a published statement of profit/loss or published financial statement (with a positive outcome) <p>The potential business failure of a regulated entity that holds cannabis is of major importance to ODC. The focus of requesting this information is to ensure that sufficient financial experience and reserves exist, so the delegate can reasonably assume business robustness and longevity.</p>

The Applicant is a Body Corporate

Questions	Brief description
List the names, dates of birth and addresses of all directors and officers of the body corporate:	<p>ODC will require the names, dates of birth and addresses of each person holding a relevant position to enable fit and proper person checks.</p> <p>Where a large business is involved, the details of the officers should be limited to persons that:</p> <ul style="list-style-type: none"> would be involved with cannabis or cannabis material during the course of their duties would be in charge of such persons would be privy to the operations associated with the cannabis, or cannabis material (if the licence were granted)
Has any director or officer of the body corporate, or the body corporate, been convicted at any time of an offence against a law of the Commonwealth, a State or a Territory or another country?	<p>ODC will require a statement in the application regarding any conviction(s) of the body corporate, its directors or officers, including the nature of the conviction and when it occurred.</p> <p>ODC must determine if the body corporate is fit and proper to hold a cannabis licence. The intent of this requirement is to exclude criminal elements or organised crime from access to medicinal cannabis, or from holding a cannabis licence.</p> <p>ODC will liaise with other agencies to validate this information and failure to identify director(s) or officer(s) that has been convicted of an offence may result in application rejection or the revocation of a cannabis licence if such information comes to light at a later date.</p>
If the body corporate is applying for a medicinal cannabis or cannabis research licence, has the body corporate, or any directors of the body corporate, engaged in conduct (that may or may not have led to a conviction) constituting a serious offence involving cultivation, supply, or use of cannabis?	<p>If you answer 'Yes' to this question, ODC will request details under Section 14J of the <i>Narcotic Drugs Act 1967</i> after your application has been submitted. This allows for protections against self incrimination which means ODC cannot provide these details to police for investigation.</p> <p>Do not include any details of the conduct in the application form as protections against self-incrimination do not apply and ODC may be required to disclose to law enforcement agencies depending on the nature of the offences.</p> <p>If you answer 'Yes', you must provide a full disclosure of the offence(s) in order for the ODC to be able to consider the grant of a licence. If it is discovered that you have not fully disclosed all conduct that would constitute a 'serious offence', these are grounds for refusal of the application or revocation of the licence.</p>

Questions	Brief description
<p>Has any director or officer of the body corporate, or the body corporate, ever had a civil penalty imposed upon them, at any time, under a law of the Commonwealth, a State or a Territory?</p>	<p>Full disclosure of all conduct constituting a serious offence is not a guarantee of gaining a licence. ODC will take the nature and circumstances of the offences into account in determining whether or not to grant the licence.</p> <p>ODC will require a statement regarding any civil penalties imposed, including the basis for the civil penalty, the date it was imposed and the value of the penalty. This information may demonstrate that the body corporate, a director or an officer of the body corporate is not fit and proper to hold a cannabis licence.</p> <p>ODC will liaise with other agencies to validate this information and failure to identify a director(s) or officer(s) that has been convicted of an offence may result in application rejection or the revocation of a cannabis licence if such information comes to light at a later date.</p>
<p>Has any revocation or suspension of a licence or permit (however described) held by the body corporate occurred under a law of the Commonwealth, a State, a Territory or another country, being a law relating to the prohibition or regulation of drugs?</p>	<p>ODC will require a statement including details of the regulatory activity, the penalty imposed (if any) and the value of the penalty linked to previous or current revocations and suspensions of licences. This may demonstrate that the body corporate is not fit and proper to hold a cannabis licence.</p> <p>ODC will liaise with other agencies to validate this information.</p> <p>It is suggested that compliance with this criteria is included in the suitability review of directors and officers in the company. A prudent company may build this type of review into its operating principles to prevent an inadvertent change in compliance on this aspect.</p>
<p>Does the body corporate, its directors or officers have any connections or associations with other people that may affect the reputation, character, honesty or professional or personal integrity of the directors or officers:</p>	<p>A statement is required to identify connections and associations to the body corporate and its directors and officers, who may have an effect on the applicant and influence the operations of the cannabis licence. The focus of the question is to determine whether any decision makers or persons handling the affairs of the body corporate may be subject to influence that would affect compliance with the conditions of the licence. ODC must consider such connections when assessing an application.</p> <p>You must identify all business associates. Further, individuals in this group should hold a National Police Check Certificate from their state of residence; copies of which will be required in the processing of this application. If this is not possible</p>

Questions	Brief description
	(e.g. an associate is based offshore) then written consent may be requested from that person for ODC to obtain this information from law enforcement agencies. The onus rests with the applicant to ensure these requirements are met.
<p>List below each person who holds a relevant financial interest, or who is entitled to exercise a relevant power (either in their own right on behalf of another person), in relation to:</p> <ul style="list-style-type: none"> • the body corporate undertaking the activities to which this application relates; and/or; • any other business the body corporate undertakes and provides a substantial portion of its income. 	<p>The applicant must provide a list of all the people that can influence the business due to the financial interest they have or because they hold a power over, or can substantially influence decision making in relation to this business, or any other business in which the body corporate is actively involved. The applicant must explain the relationship between other businesses and how that income relates to the potential cannabis licence the body corporate is applying for.</p> <p>You need to outline how the person(s) holding financial interest can exert power over the business (in the event a cannabis licence was to be granted). Such persons may negatively influence the decision making process if they:</p> <ul style="list-style-type: none"> • have known links to criminal organisations • have a criminal history or served a custodial sentence • have had a civil penalty imposed on them • have a history of bankruptcy
<p>Do any directors or officers of the body corporate hold, or have they ever held, a professional qualification(s) issued under a law of the Commonwealth, a State or a Territory?</p>	<p>The applicant needs to identify the qualifications of the directors and key officers handling the affairs of the business.</p> <p>The focus of requesting this information is to determine the maturity of the body corporate in making sound business decisions and being able to comply with regulatory requirements.</p>
<p>Are there any matters that may affect whether the directors or officers of the body corporate are of good repute, relating specifically to their character, honesty and professional and personal integrity:</p>	<p>This question is concerned with identifying whether directors and/or officers have connections or associations with any person or party that may have the ability to adversely affect their honesty or professional decision making or personal integrity. This may be a risk factor in the overall compliance of the facility in the event a licence was granted. The types of connections or associations to persons with which they are involved include cohorts, 'cronies', 'mates', special interest groups or clubs.</p> <p>Some examples of association that ODC may seek further information about are between that person and any person:</p> <ul style="list-style-type: none"> • with known links to criminal or outlawed

Questions	Brief description
	<p>organisations</p> <ul style="list-style-type: none"> with a criminal history or served a custodial sentence who has had a civil penalty imposed <p>This should also include any family member who has known links to a criminal/outlawed organisations or a business associate who has been convicted of a crime.</p> <p>ODC may request an individual fit and proper person statement from directors or officers to identify any connections or associations they may have with people who could influence the operation of a business with access to and/or control of cannabis or other narcotics.</p> <p>ODC will liaise with other agencies to validate this information and failure to identify an association that may affect your reputation, character, honesty, or professional or personal integrity may result in application rejection or the revocation of a cannabis licence if such information comes to light at a later date.</p>
<p>Does the body corporate hold, or has it previously held, a licence issued under the <i>Narcotic Drugs Act 1967</i>:</p>	<p>If the body corporate has ever held a licence issued under the <i>Narcotic Drugs Act 1967</i> you should provide:</p> <ul style="list-style-type: none"> the licence number the licence type the licence status (whether the licence is current, expired, revoked or suspended)
<p>Are there any issues you wish to bring to the attention of the ODC relating to the body corporate's compliance with the <i>Narcotic Drugs Act 1967</i>. If there are no compliance issues, please write 'Nil':</p>	<p>A statement should detail any non-compliance with the Act. ODC will consider this statement in determining if the body corporate is fit and proper to hold a cannabis licence.</p>
<p> Please attach a completed Informed Consent form for each person employed by the applicant to carry out the activities authorised by the licence (e.g. directors and/or officers, shareholders and/or business associates that have over 5% of shares in the Body corporate and/or a seat on the board, and/or voting rights/ and/or other influence over operations).</p>	<p>ODC must be provided with a completed Informed Consent form. ODC may approach law enforcement and other agencies to obtain relevant information.</p>

Questions	Brief description
 Please attach a current Company Extract issued by the Australian Securities and Investments Commission (ASIC).	<p>ODC must be provided with a Company Extract which contains details of any shareholders and the proportion of the shares of any such people have in your company.</p>
 Please attach a resume detailing your previous business experience.	<p>An extensive resume is not required, however, you should include a summary of your business experience.</p>
 Please attach evidence (e.g. a bank statement or audited financial statement) that you have a sound and stable financial background and that there are no financial circumstances that may limit your ability to comply with a licensee's obligations under the <i>Narcotic Drugs Act 1967</i> .	<p>The request for financial background evidence may be met by providing one of the following examples:</p> <ul style="list-style-type: none"> • a statement from a financial institution(s) showing financial reserves • a financial audit report by a suitably qualified person (with a positive outcome) • a published statement of profit/loss or published financial statement (with a positive outcome) <p>The potential business failure of a regulated entity that holds cannabis is of major importance to ODC. The focus of requesting this information is to ensure that sufficient financial experience and reserves exist, so the delegate can reasonably assume business robustness and longevity.</p>

The Applicant is a crown agency

Questions	Brief description
<p>Provide details of how the agency will satisfy fit and proper person requirements.</p>	<p>The ODC must be satisfied that fit and proper person requirements will be met through your agency's practices governing the persons authorised to control authorised activities (if the licence were granted).</p>

Annex D – Section 4: Licence module

Questions relating to	Brief description
<p>This application is for a</p> <ul style="list-style-type: none"> Manufacturing licence for narcotic drugs (only when also applying for either a medicinal cannabis licence or cannabis research licence) Medicinal cannabis licence Cannabis research licence <p>Note: while it is possible to apply for manufacturing only using these forms and modules, it is preferred that you refer to the manufacturing section of the ODC website and complete the relevant standalone manufacturing application.</p>	<p>There are three fundamental choices of licence type. The actual activities that are covered by these steps are defined in the United Nations Office of Drugs and Crime publication - <i>Single Convention on Narcotic Drugs</i>.</p> <p>A Manufacturing licence for narcotic drugs authorises steps of manufacture on cannabis or cannabis material for the purpose of patient treatment or research.</p> <p>Cannabis and opiates are narcotics under the prevailing legislation. The <i>Manufacturing licence for Narcotic Drugs</i> may also cover manufacture with opiates and/or cannabis. Therefore, the information under this selection seeks details on drug(s) derived from either cannabis or opiates. This gives rise to a number of questions regarding the presence of cannabis or opiates.</p> <p>A medicinal cannabis licence authorises the cultivation and/or production of cannabis or cannabis material for human treatment purposes.</p> <p>A cannabis research licence authorises the cultivation/production and/or manufacture of cannabis, or cannabis material, for the purposes of research. This licence type does not cover the supply of cannabis or cannabis material for human usage. Research may be agricultural, physicochemical and other forms.</p>

Manufacturing licence for Narcotic Drugs Selection

Questions relating to	Brief description
Drug proposed for manufacture	<p>The name of the drug should be identified. If the Drug has an officially approved name in Australia or an overseas jurisdiction, this should be used.</p> <p>If the drug is yet to be authorised, the active ingredient, unit dosage form and the strength per unit should be provided.</p>

Questions relating to	Brief description
Proposed end use of drug	<p>The applicant needs to identify the end use.</p> <p>If directly for human treatment, the relevant treatment regime and indications should be given, e.g. <i>Two tablets per day for treatment of symptoms of diagnosed migraine.</i></p> <p>If for further processing, then the party receiving the cannabis drug for further processing should be identified in addition to the final drug itself (as per above).</p> <p>If for research, then the nature of the objectives should be briefly stated.</p>
Do you intend to manufacture a drug that includes, or is derived from, any part of the cannabis plant?	<p>By default this is set to 'Yes' to signify that at least one of the drugs to be manufactured contains cannabis or cannabis material.</p> <p>Alternatively, this may be changed to 'No' if subsequent medicines are opiate based.</p> <p>Importantly, setting the response to this question to 'No' will imply that the application covers only opiates, in which case the incorrect application has been chosen and you should visit the manufacturers section of the ODC website.</p>
Is the drug for the purposes of research relating to medicinal cannabis products?	<p>Select 'Y' if the drug is to be used for research purposes relating to research directly into drugs for human patient treatment. This does not mean clinical trials, but rather research on the drug itself or pre-clinical research.</p> <p>Selecting 'Yes' will open two questions seeking information of the study and the principal person(s) conducting the research.</p>
Is the drug a medicinal cannabis product?	<p>'Yes' should be selected if cannabis and cannabis material is produced to undergo further manufacture to reach its final medicinal form. E.g. an extract that is medicinal in its own right but will undergo manufacture.</p> <p>Selecting 'No' identifies that the manufacturing product does not contain cannabis.</p>
Is the drug to be supplied to the public?	<p>'Yes' is selected if the drug is for supply under the authority of the <i>Therapeutic Goods Act 1989</i>. Details of the approval authorising public supply should be provided if possible, e.g. Aust R number.</p>
Is the drug to be used in clinical trial	<p>If 'Yes' is selected then the applicant holds a Clinical Trial Notification tracking number from the Therapeutic Goods Administration (TGA) or is working towards this. Evidence of this may be requested.</p>

Questions relating to	Brief description
Add drug	<p>Selecting this will allow you to provide details of the range of drugs that are to be manufactured under the proposed licence.</p> <p>Details of all drug(s) must be included when 'Add drug' is selected.</p>
Detail the proposed business activities to be conducted under licence	<p>The actual nature of the activities that you will perform on the cannabis, or cannabis material, needs to be documented, e.g. refinement of the cannabis products to produce an extract.</p> <p>Details of the projected mass of cannabis and the final products should be specified, as should the approximate timing of activities.</p>
Has the applicant applied for, or does the applicant intend to apply for, another licence under the <i>Narcotic Drugs Act 1967</i> *	<p>It is important that ODC understands how this application relates to other authorised activities involving narcotics that may have been approved and conducted or not yet authorised but are planned. By selecting 'Yes' you are presented with a prompt to identify the intended application, i.e. those that are currently planned for but not yet executed and are relating to narcotics (cannabis/opiates), e.g. import and export.</p> <p>The answer 'None' may be provided if no further applications are held or intended at this time.</p> <p>This will be followed by questions regarding existing applications lodged with ODC for authorised activities involving narcotics (cannabis/opiates). Details including the licence number and type will be required. This refers to the approval details provided by ODC in relation to these applications.</p>

Cannabis Research Licence Selection

It is recommended that you discuss the details of your research program with ODC prior to completing the application.

Questions relating to	Brief description
Selection of: <ul style="list-style-type: none"> • Non-commercial research • Commercial research 	This selection will identify if the research is to be conducted as a not for profit activity or is related to a commercial research venture.
Selection of: <ul style="list-style-type: none"> • Cultivate cannabis • Produce cannabis 	<p>These activities are defined under the <i>Narcotic Drugs Act 1967</i> to align with their meaning in the <i>Single Convention on Narcotic Drugs 1961</i>. Both activities may be selected if this is required.</p> <p>Applying for a licence that authorises cultivation of cannabis does not allow for <i>production</i> activities to be conducted without approval. However, for cannabis, it must undergo <i>production</i> after <i>cultivation</i>. Only a party that is approved to conduct <i>production</i> of cannabis plants can do so. A licence for cannabis cultivation will be questioned if no <i>production</i> arrangements are stated and refused if no arrangements exist.</p>
Provide a summary of the cultivation and/or production activities that you propose to undertake, including how the outcome of this research relates to medicinal cannabis	An overview needs to be provided that allows the assessor to understand the link between the authorisation you are seeking in this application (for research purposes) and an objective that supports medicinal advancement(s) in relation to cannabis.
Confirm the full range of activities sought for authorisation:	In normal operations, some activities involving cannabis may need to occur off site. You must declare the situations in which this will occur and explain the purpose of each movement.
Provide details of the funding, financial assistance and other resources that will enable the applicant to carry out the research mentioned above	It is important to the ODC that no institution terminates a research activity while controlling cannabis or cannabis material. You need to provide an overview that demonstrates sufficient resources are in place in the researching institution to prevent the aforementioned scenario.
Please attach a resume detailing the qualifications and expertise of the person conducting the research	There should be a link between the persons for whom the resume is provided and the brief summary of the research. The persons identified in this resume should be connected with the institution or a related research institution and have established research credentials and qualifications.

Medicinal cannabis licence selection

Questions relating to	Brief description
<p>Selection of 'Cultivate medicinal cannabis' only</p> <p>Please provide details of the arrangements in place between the applicant and the holder of a medicinal cannabis production licence</p>	<p>This activity is defined under the <i>Narcotic Drugs Act 1967</i> (Cth) to align with its meaning in the <i>Single Convention on Narcotic Drugs 1961</i>.</p> <p>A licence that authorises cultivation of cannabis does not allow for <i>production</i> activities to be conducted without approval. Only a party that is authorised to conduct <i>production</i> of cannabis plants can do so. Cannabis cultivation will not be allowed if no further <i>production</i> arrangements are planned or in place.</p> <p>The focus of this question is to clarify the arrangements in place between you (the applicant) and the party potentially engaged to conduct cannabis <i>production</i> activities (the holder of a cannabis production licence). You should:</p> <ul style="list-style-type: none"> • identify the party intending to conduct the cannabis production activities • give the cannabis licence identification for the above party or give the application ID if this approval is anticipated • estimate the dates and duration of the activity • define where the cannabis products will be stored post production • identify whether any other parties are involved • describe the responsibilities of each party
<p>Selection of 'Produce medicinal cannabis' only</p> <p>or</p> <p>Selection of 'Cultivation of medicinal cannabis' and 'Production of medicinal cannabis'</p> <p>Please provide details of the arrangements in place between the applicant and the holder of a Narcotics manufacturing licence</p>	<p>These activities are defined under the <i>Narcotic Drugs Act 1967</i> (Cth) to align with their meaning in the <i>Single Convention on Narcotic Drugs 1961</i>. The act of refining or transforming cannabis or cannabis resin, to another material, exceeds the steps that may be conducted under production and requires the grant of a manufacture licence under the <i>Narcotic Drugs Act 1967</i> (Cth).</p> <p>A licence that authorises cultivation of cannabis does not allow for <i>production</i> activities to be conducted without approval. Only a party that is authorised to conduct <i>production</i> of cannabis plants can do so. Cannabis cultivation will not be allowed if no further <i>production</i> arrangements are planned or in place.</p> <p>The focus of this question is to clarify the arrangements in place between you (the applicant) and the party potentially engaged to conduct such <i>manufacturing</i> activities (being be the holder of a manufacture licence). You should:</p> <ul style="list-style-type: none"> • identify the party intending to conduct the manufacturing activities

Questions relating to	Brief description
	<ul style="list-style-type: none"> • give the manufacture licence identification for the above party or give the application ID if this approval is anticipated • estimate the dates and duration of the activity • define where the cannabis products will be stored post production • identify whether any other parties are involved • describe the responsibilities of each party
Outline what business activities will be conducted under the license, including an estimate of the size and scope of cultivation and production and any other business activities	<p>The nature of the business activities that you will perform on the cannabis or cannabis material needs to be documented. Details of the projected mass of cannabis and the final products should be specified as should the approximate timing of activities.</p> <p>It is important that you also identify any other external enterprises that would be involved in your business activities involving cannabis or cannabis material, e.g. contractors and service providers.</p>
Confirm the full range of activities sought for authorisation:	In normal operations, some activities involving cannabis may need to occur off site. You must declare the situations in which this will occur and explain the purpose of each movement.

Annex E – Section 5: Security details

Questions relating to	Brief description
<p>Provide details of the measures that will be in place to ensure the physical security of cannabis plants, cannabis or cannabis resin, drugs or starting material:</p> <ul style="list-style-type: none"> a. in the applicant's possession or control, or b. obtained, cultivated or produced, or manufactured under the licence 	<p>You are required to provide your proprietary security plan which details the measures that will be in place to ensure the physical security of cannabis plants, cannabis or cannabis resin in the applicant's possession or control; and obtained, cultivated or produced under the proposed licence. As a minimum, this needs to meet the relevant expectations prescribed in the Guideline: Security of Medicinal Cannabis.</p>
<p> Please attach your proprietary security plan, labelling this document 'Security Plan'</p>	<p>Attaching a 'proprietary document' means providing a copy of your organisation's documentation (procedures) covering this security aspect. This should be recognisable as an operational/instructional document belonging to your organisation. If your security plan is large, you may consider dividing the document into separate chapters.</p>

Annex F – Section 6: Risk management and standard operating procedures and policies

Question/Request	Brief guidance
<p>Please provide an overview of how risk management will be applied</p> <p> Please attach your proprietary risk management plan, labelling this document 'Risk management plan'</p>	<p>The term overview means that you provide details of who is responsible for risk management planning in your organisation, how often is it updated, in what way risks are raised to your management, who puts risk reduction steps into place and any other relevant information on the risk management approach.</p> <p>A copy of the risk management plan is needed for review to confirm it is a strategic document belonging to your organisation, covers the necessary risk aspects and is consistent with the overview you have provided.</p>
<p>Provide a list of the standard operating procedures and policies that will be used to undertake the (licenced) activities and provide a copy of each document</p> <p> Please attach your proprietary standard operating procedures and policies, labelling each document 'SOP – [insert activity]' (e.g. SOP – Recruitment)</p>	<p>It is necessary to provide copies of your standard operating procedures and policies that will be used to undertake the activities. At a minimum, this should include standard operating procedures and policies that address:</p> <ul style="list-style-type: none"> • measures to prevent unauthorised access (physical and electronic) • arrangements to control persons entering the site • equipment and other arrangements to prevent, monitor, detect and record unauthorised access • arrangements for the physical security of cannabis • arrangements to ensure loss and theft of cannabis is detected and reported immediately • arrangements to ensure the safe and secure disposal or destruction of cannabis is detected and reported • arrangements to ensure the safety and security of the supply, delivery and transportation of cannabis • arrangements in place with emergency services, police and local government authorities to deal with loss, theft, spoilage, disposal or destruction of cannabis • records management.

Checklist: Documents you need to attach to your application

Document	Attached
3 certified true proof of identity documents with at least one from Category A (individual only)	
Site plan showing how the land will be used	
Floor plan of the premises and facilities	
Completed and signed Informed Consent form	
Resume detailing your previous business experience	
Evidence that you have a sound and stable financial background	
Current company extract issued by the Australian Securities and Investments Commission (ASIC) (body corporate only)	
Resume detailing the qualifications and expertise of the person conducting the research (cannabis research licence only)	
Security plan	
Risk management plan	
Standard operating procedures	