



Application for Declaration

that specified information is confidential commercial information (CCI)

1. Applicant organisation name:	Enter name
2. Accreditation number: (If the organisation is accredited by the Gene Technology Regulator.)	Enter number
3. Usually, <i>Applications for declaration that specified information is CCI</i> are for information that has been included in another application. Does this application accompany:	<input type="checkbox"/> a DIR licence application OR <input type="checkbox"/> a DNIR licence application OR <input type="checkbox"/> a document not listed above?
4. Provide the OGTR reference number, if known, for the application, or other document referred to in 3, e.g. DIR or DNIR number or reference number from an online application form.	Enter the OGTR reference number, if known
5. Provide the title of the application, referred to in 3.	Enter title of application or document

Information for applicants

Contact us

We encourage prospective Confidential Commercial Information (CCI) applicants to contact the OGTR before submitting a written application to discuss information requirements or ask any questions about this form.

You may call (1800 181 030) or email us (ogtr.applications@health.gov.au).

What is this application form for?

This form is to apply for a declaration that specified information is CCI under the *Gene Technology Act 2000* ([the Act](#)) and corresponding state law. The Gene Technology Regulator (the Regulator) needs the information you provide in this form to determine whether or not to make such a declaration. More information about CCI is available in the [CCI Form Information](#) document.

How should you fill out this form?

- Read through all the questions, including the guidance text in italics, and also the separate [CCI form Examples](#) document before filling out the form. Links to examples for specific questions are provided in this form (as 'Examples (p1)'). Links will take you to the document but not the specific page). This will help focus your answers on the information we need to complete our evaluation.
- There is guidance available about the form in general and about how to provide answers to some individual questions in this application form. This is provided in a separate information document. Please

refer to the [CCI Form Information](#) document as indicated in this form (as 'Information (p1)'). Links will take you to the document but not the specific page.

- Ensure you answer each relevant question in sufficient detail. Not providing the required information could delay a decision on the application or may lead to the application being refused. It may also delay consideration of an application for a licence, certification or accreditation to which the specified information relates.
- Ensure you answer each question to the best of your knowledge. Deliberately providing false or misleading information is a punishable offence (section 192 of the Act).
- Ensure you answer each question with adequate supporting material. Information should be specific, comprehensive and supported by evidence. We may ask you to provide copies of journal publications and unpublished information.
- Modifying text formatting in this form can be difficult. However, if you first draft the answer in a separate document and then paste it into the answer field, it should retain its formatting. Alternatively, you may provide those answers in attachments. Clearly reference any attachments you provide in response to a question and cross-reference each attachment to the applicable question.
- Do not repeat information. If necessary, refer to your answer to other questions.

How can you submit this form?

Once you have completed the form and obtained the relevant signatures (Part 3 of this form):

- Email the completed application form electronically **in a searchable format** to: ogtr.applications@health.gov.au (see below for instructions); or
- Mail the application files on a USB stick via Express Post to: Office of the Gene Technology Regulator, MDP 54, GPO Box 9848, Canberra, ACT, 2601

Applications containing confidential information can be transmitted securely using the Australian Government's Health Data Portal or the secure email service used by the Department of Health and Aged Care. For assistance with establishing access to either of these, contact ogtr.applications@health.gov.au. Access to the Australian Government's Health Data Portal takes time to set up, so please allow up to 3 weeks for access to this service and contact us as soon as possible to arrange access.

If you choose to provide confidential information by standard email, be aware that this is transmitted via an unclassified internet connection and will not be protected in the process. OGTR staff will securely store the confidential information once received.

How CCI is used

If you submit an application for declaration that specified information is CCI, the information will be treated as CCI by OGTR until the Regulator declares or refuses to declare that the information is CCI. The Regulator and OGTR staff must not disclose CCI, except to make it available to the scientific experts and government agencies that are consulted by the OGTR during the decision-making process or as otherwise required by the Commonwealth, a Commonwealth authority or a State agency to carry out duties or functions under the Act or a corresponding State law. Please see the [OGTR website](#) for general information on CCI and a [factsheet](#) on how we treat CCI.

What is the application fee?

There is currently no application fee.

What will happen after you have submitted the application?

We will acknowledge receipt of the application by email. Our office will then conduct an initial screening of the application to ascertain completeness for the purpose of assessment. If the application is sufficiently complete to be accepted for evaluation, we will assign it an OGTR reference number and send the reference number by email. Cite this reference number whenever you contact us regarding the application.

Contact us (ogtr.applications@health.gov.au) if we have not acknowledged receipt of the application within two weeks of submission.

Need more information?

More information about CCI and this form can be found in the [CCI form Information](#) document which can be accessed or downloaded from the [OGTR website](#).

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Section 1 Applicant Details

Part 1A Applicant Type

This information is required to establish whether your application is for specified information which relates to the Act or to your corresponding State legislation. It is advisable to check with your organisation's legal area before completing this Part.

1A 1 This application is being made by:

- a natural person
- an organisation

1A 1.1 Information about the applicant organisation type

If the application is by an organisation, indicate below which of the following best describes your organisation. You may need to tick more than one box.

1A 1.1.1 For an organisation which is a constitutional corporation, i.e. a trading, foreign or financial corporation within the meaning of paragraph 51(xx) of the Constitution, is the organisation a:

- Higher Education Institution
- Hospital
- Research Institute or similar
- Commonwealth Authority which is a body corporate established under an Act and/or a company in which a controlling interest is held by the Commonwealth or a Commonwealth authority
- State instrumentality which is a body corporate established under an Act and/or a company in which a controlling interest is held by that State or by a State instrumentality
- Corporation which is none of the above? Please provide details.

Enter details.

1A 1.1.2 For an organisation which is NOT a constitutional corporation, is the organisation a:

- Higher Education Institution
- Hospital
- Research Institute or similar
- Commonwealth Department
- State Government Department
- Organisation which is none of the above? Please provide details.

Enter details.

Part 1B Authorised Person for the Application

Please provide details for a person who is either the applicant or authorised to act on behalf of the applicant for this application. An OGTR evaluator may contact this person with any queries about this application.

Surname:	Enter name
First name:	Enter first name
Personal title, e.g. Ms/Mr/Dr:	Enter title
Job title:	Enter job title
Organisation:	Enter organisation
Phone number:	Enter phone number
Mobile number:	Enter mobile number
Email address:	Enter email address
Street number and name:	Enter street number and name
Town/city:	Enter town/city
State/territory:	Enter state/territory
Postcode:	Enter postcode
Country:	Enter country
Postal address, if different:	Enter postal address

Section 2 Information in support of the application

Under s184(1) of the Act, a person may apply to the Regulator for a declaration that specified information to which this Act relates is confidential commercial information (CCI) for the purposes of this Act.

The Regulator can only declare information that is provided as CCI. This application must specify and identify all information for which you are seeking a declaration as CCI and provide valid justification for each piece of information as to how it meets the statutory criteria to be considered CCI.

Please note that personal information has protections under the *Privacy Act 1988* and the *Freedom of Information Act 1982*. The OGTR does not disclose personal information to a third party or the public unless required by law. If you have questions about protection of personal information, please contact the OGTR before completing your application for declaration of CCI.

[Information](#) (p3)

Part 2A Information in relation to which a declaration is sought

[Information](#) (p4)

2A 1 Please specify from either your DIR or DNIR application or other document, the exact information for which you are seeking a declaration of CCI.

[Information](#) (p4)

[Examples](#) (p1)

Enter the specific information for which you are seeking a declaration of CCI.

2A 2 Have you previously applied for some or all of this information to be declared CCI by the OGTR?

Yes No

If No, proceed to Question 2A 3.

If Yes, please provide the CCI declaration number(s) (if known) or identifier.

[Information](#) (p4)

Enter details.

2A 3 For each piece of information listed in 2A 1 and 2A 2, please provide the location of the information within the submitted document(s).

[Information](#) (p5)

[Examples](#) (p3)

Enter your answer

2A 4 Is your specified information related to a DIR application?

[Information](#) (p5)

Yes No

If Yes, complete Question 2A 5.

If No, proceed to Part B.

2A 5 Provision of documents from which all requested CCI has been removed.

Information (p5)

If your specified information relates to a DIR application, then for each document identified in 2A 3 you are required to supply an expurgated copy from which you have removed all requested or previously declared CCI. If you are unable to provide an expurgated copy please explain why.

Examples (p3)

Provide the document title(s) for all expurgated documents you are supplying.

Ensure the documents are titled in the following format: 'Expurgated copy of [original title]'.

Table 2A 5

Expurgated document title

Add extra rows if needed

You must attach a copy of the expurgated document(s) as named above when you submit this CCI application form.

List all documents for which you are not able to provide an expurgated copy and for each document explain why you are unable to.

Enter title(s) for each unexpurgated document here together with a statement of reason(s)

Part 2B Justification for treatment of information as CCI

The information for which you are seeking a declaration of CCI must meet criteria set out in section 185(1) of the Act. It is recommended that you **seek your own legal advice** to determine whether the specified information meets these criteria before completing this form.

Section 185(1) of the Act states that:

- (1) Subject to subsection (2), if the person satisfies the Regulator that the information specified in the application is:
- (a) a trade secret; or
 - (b) any other information that has a commercial or other value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed; or
 - (c) other information that:
 - (i) concerns the lawful commercial or financial affairs of a person, organisation or undertaking; and
 - (ii) if it were disclosed, could unreasonably affect the person, organisation or undertaking;

the Regulator must declare that the information is confidential commercial information for the purposes of this Act.

For each piece of information identified in Section 2 Part A, for which you are seeking a declaration as CCI, you will need to provide evidence of how it meets one of the above criteria by answering the appropriate questions in sections B1, B2 and B3.

[Information](#) (p6)

Information that is a trade secret – s185(1)(a)

2B 1 Is any of the information a trade secret?

[Information](#) (p7)

Yes No

If No, proceed to question 2B 2.

If Yes, please complete the table and address the following 2B 1 sub-questions.

Information as identified in question 2A 1 - seeking protection as a trade secret

Add extra rows if needed.

2B 1.1 Is your information used or useable in an identifiable trade or business?

Yes No

If Yes, what trade or business?

Enter your answer

2B 1.2 Is the information available in the public domain?

Yes No

2B 1.2.1 If Yes, on what basis do you regard it as a Trade Secret?

Enter your answer

2B 1.2.2 Have you conducted searches to determine whether the information for which you are seeking CCI is available in the public domain?

Yes No

If Yes, describe the searches undertaken.

[Information](#) (p7)

Enter your answer

If No, how can you confirm that the information is not available in the public domain?

Enter your answer

2B 1.3 Is the information known outside your organisation?

Yes No

If Yes, how is the information protected as a trade secret outside your organisation?

[Information](#) (p7)

Enter your answer

2B 1.4 Have you taken any measures to guard the secrecy of the information?

Yes No

If Yes, describe the measures taken.

[Information](#) (p7)

Enter your answer

2B 1.5 Does the information have value to you?

Yes No

If Yes, provide a thorough explanation, including concrete examples.

Enter your answer

2B 1.6 What harm would release of the information do to your organisation? If no harm, how does it merit protection as a trade secret?

Enter your answer

2B 1.7 Do you have any knowledge of whether the information provides you with an advantage over your competitors?

Yes No

If Yes, describe how the information gives you an advantage over your competitors.

Enter your answer

2B 1.8 Have you spent resources in developing the information?

Yes No

If Yes, provide indicators of time, effort, and/or money spent on developments undertaken.

Enter your answer

2B 1.9 Would it be easy for others to acquire or duplicate the information?

Yes No

If Yes, why can it be regarded as a Trade Secret?

[Information](#) (p7)

Enter your answer

2B 1.10 Provide any further relevant statements in support of your claim that the information is a trade secret, attaching any relevant information.

[Information](#) (p7)

Enter your answer

Information of commercial or other value - s185(1)(b)

[Information](#) (p7)

2B 2 Does any of the information have a commercial or other value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed?

Commercial Value: Yes No

Other Value: Yes No

If No, proceed to Question 2B 3.

If Yes, for either Commercial or Other value (or both), please complete the table and address the following 2B 2 sub-questions. Questions indicate whether they must be answered in relation to Commercial Value, in relation to Other value, or to both Commercial and to Other value.

[Information](#) (p8)

Information identified in Question 2A 1 that has commercial or other value	Commercial Value? (Y/N)	Other Value? (Y/N)

Add extra rows if needed.

2B 2.1 Is the information available in the public domain?

Yes No

2B 2.1.1 If Yes, how would disclosure destroy or diminish the value of the information?

Enter your answer

2B 2.1.2 Have you conducted searches to determine whether the information for which you are seeking CCI is available in the public domain?

Yes No

If Yes, describe the searches undertaken.

[Information](#) (p8)

Enter your answer

If No, how can you confirm that the information is not available in the public domain?

Enter your answer

2B 2.2 Is the information known outside your organisation?

Yes No

If Yes, how would disclosure destroy or diminish the value of the information?

[Information](#) (p8)

Enter your answer

2B 2.3 Have you taken any measures to guard the secrecy of the information?

Yes No

If Yes, describe the measures taken

[Information](#) (p8)

Enter your answer

2B 2.4 Is the information currently the subject of a patent application or an existing patent?

Yes No

If Yes, at what stage of the patent process is your application and a patent number, if known?

[Information](#) (p9)

Enter your answer

If No, is the information likely to be the subject of a patent application?

[Information](#) (p9)

Enter your answer

If your information has commercial value, please answer question 2B 2.5

If your information has other value, please answer question 2B 2.6

2B 2.5 Please provide any information you have about the monetary value of the specified information to an arms-length buyer.

[Information](#) (p9)

Enter your answer

2B 2.6 If the value to your organisation is not commercial value, please indicate what the other value of the information is to your organisation.

[Information](#) (p9)

Enter your answer

2B 2.7 To what extent would you expect the value of the information to be diminished or destroyed if disclosed?

Provide concrete and comprehensive examples.

Commercial value:

Enter your answer

Other value:

Enter your answer

2B 2.8 In the space below provide any further relevant statements in support of your claim that the information has a commercial or other value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed.

Enter your answer

Other business information – s185(1)(c)

2B 3 If the information is not a trade secret (as set out in question 2B 1) or commercially or otherwise valuable information (as set out in question 2B 2):

Does the information concern the lawful commercial or financial affairs of a person, organisation or undertaking?

And, would disclosure of the information unreasonably affect the person, organisation or undertaking?

Yes No

If Yes to both questions, complete the table and answer the following 2B 3 sub-questions.

If No, proceed to Part C.

[Information](#) (p9)

Other Information identified in question 2A 1 that concerns lawful commercial or financial affairs for which disclosure would have unreasonable effects

Add extra rows if needed.

2B 3.1 How would disclosure affect a person, organisation, or undertaking?

Enter your answer

2B 3.2 Why would these effects be unreasonable?

Enter your answer

2B 3.3 Please provide any further relevant statements in support of your claim that the information concerns the lawful commercial or financial affairs of a person, organisation or undertaking which, if disclosed, could unreasonably affect the person, organisation or undertaking.

Enter your answer

Part 2C Additional information if application for declaration is related to field trial locations

Please note that under s185(2A) of the Act the Regulator must refuse to declare that information is confidential commercial information if the information relates to one or more locations at which field trials involving GMOs are occurring, or are proposed to occur, unless the Regulator is satisfied that significant damage to the health and safety of people, the environment or property would be likely to occur if the locations were disclosed.

2C 1 Are you seeking to claim CCI for a field trial location?

Yes No

If Yes, answer the following questions.

If No, proceed to Part D.

[Information](#) (p10)

2C 1.1 If the information relating to field trial locations is disclosed, would it be likely to result in significant damage to the health and safety of people?

Yes No

If Yes, provide details and evidence

Enter your answer

2C 1.2 If this information is disclosed, would it be likely to result in significant damage to the environment?

Yes No

If Yes, provide details and evidence

Enter your answer

2C 1.3 If this information is disclosed, would it be likely to result in significant damage to property?

Yes No

If Yes, provide details and evidence

Enter your answer

2C 1.4 Is there any other information you wish to add in respect of this request related to a field trial location?

Yes No

If Yes, provide details

Enter your answer

Part 2D Public interest information

Please be aware that under s185(2) of the Act, The Regulator may refuse to declare that the information is confidential commercial information if the Regulator is satisfied that the public interest in disclosure outweighs the prejudice that the disclosure would cause to any person.

2D 1 Do you wish to provide a statement regarding possible prejudice (harm) to any person if the information were disclosed?

Yes No

If Yes, in the space below, please provide additional information not already provided about the extent to which prejudice, or harm, to any person, connected to this application or not, that would be caused as a result of disclosure of the information.

Provide additional information regarding any prejudice.

Enter your answer

2D 2 Do you wish to provide a statement regarding any public interest in disclosing the information?

Yes No

If Yes, in the space below, please provide your statement.

Enter your answer

Section 3 Signatures and consent to the release of documents

If you believe you would need to answer 'No' in response to any of these statements, please contact the OGTR to discuss before completing this form. By phone: 1800 181 030 or by email: ogtr.applications@health.gov.au

[Information](#) (p11)

I declare that:

- I am the applicant, or duly authorised by the natural person or organisation, making this application, to sign this declaration; and
- the information supplied in this application and attachments (if any) is true and correct at this time; and
- I am aware that the making of a false or misleading statement may be punishable by imprisonment or a fine under the *Gene Technology Act 2000* or a corresponding state law.

Yes No

[Information](#) (p11)

If your application for declaration that specified information be declared CCI does not relate to information for a DIR licence application, please proceed to the signatures section and complete the form by signing.

If your application for declaration that specified information be declared CCI relates to information for a DIR licence application, please complete the following before signing.

I hereby give my consent to the disclosure by the Office of the Gene Technology Regulator (OGTR) of the documents and all information contained in the documents I have listed at Table 2A 5.

Yes No

[Information](#) (p11)

I understand that the Gene Technology Regulator may provide the expurgated documents at Table 2A 5, and any other document as required by law, to a person making a request under section 54 of the *Gene Technology Act 2000* in relation to a DIR licence application without further notification to the applicant.

Yes No

I confirm that I have taken measures to ensure that the expurgated documents at Table 2A 5 do not contain any information which is confidential commercial information (CCI), or information which has been previously declared CCI or information which is the subject of this or another application for a declaration for CCI.

Yes No

I agree that the responsibility to remove CCI from the expurgated documents at Table 2A 5 remains with the applicant and that, in the event that one or more of the expurgated documents contains CCI, this consent authorises the disclosure by the OGTR and the applicant shall not hold the Commonwealth or its agents and employees in any way liable for any damage that may be incurred by any person or organisation as a consequence of that disclosure.

Yes No

[Information](#) (p11)

Print name:	Print name
Signature:
Job title:	Enter job title
Date:	Select date

If signing on behalf of an organisation, please also complete the following declaration.

I declare that I am duly authorised to sign this consent on behalf of	Enter organisation name
Print name:	Print name
Signature:
Job title:	Enter job title
Date:	Select date